User's Manual

PC Classic

PC Classic Plus

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Obtaining Warranty Service

Warranty service may be obtained by calling Spirometrics customer service at 1-800-767-0004 (USA).

PC CLASSIC / PC CLASSIC PLUS USER'S MANUAL

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Spirometrics Medical Equipment Company

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http://www.spirometrics.com

IMPORTANT!

Please send in the attached card to activate your warranty.

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Table of Contents

Specifications i
Models i
General ii
Electrical iii
Operating iii
Environmental iii
Chapter 1: Introduction 1
1.1 Welcome 1
1.2 Product Differences: PC Classic vs. PC Classic Plus 1
1.3 Warranty 2
Chapter 2: Safety 5
2.1 Intended Use 5
2.2 Warnings and Precautions 5
2.3 Disposal 7
2.4 Symbols and Definitions 7
Chapter 3: Equipment Preparation 9
3.1 Preparing for Installation 9
3.1.1 Inventory 9
3.1.2 Connecting the Classic Sensor 10
3.2 Software Installation 11
3.2.1 Initial Setup Wizard 12
3.2.2 Welcome Window 12
3.2.3 Sensor Found Window 13
3.2.4 Address Window 14
3.2.5 Ambient Conditions Window 15
3.2.6 Access Codes Window 16
3.2.7 Attaching the 3-Liter Syringe 18
3.2.8 Performance Verification Routine (*PC Classic only*) 19
3.2.9 Calibration (*PC Classic Plus only*) 23
Chapter 4: Test Preparation 31
4.1 Processing Patient Data 31
4.1.1 Entering a New Patient 31
4.1.2 Retrieving and Modifying Patient Information 38

4.1.3 Deleting Patient Information 40
Chapter 5: Testing 42
5.1 Optional Pre-Test Training (*PC Classic Plus Only*) 42
5.2 FVC Test 45
5.2.1 Warning Messages 52
5.3 VC Test 52
5.4 Post-Bronchodilator Testing (*PC Classic Plus Only*) .. 56
5.4.1 Method 1: 56
5.4.2 Method 2: 59
5.5 MVV Test (*PC Classic Plus Only*) 61
5.5.1 View or Delete Test 66
5.6 Summary Report 67
5.7 Trend Analysis 72
Chapter 6: Special Features 77
6.1 Customization 77
6.1.1 Software Customization 77
6.1.2 Data Options 79
6.1.3 Report Setup 81
6.1.4 Report Options 83
6.1.5 Methacholine Challenge Options 84
6.1.6 Licensing 86
6.1.7 General Customization Buttons 87
6.2 Performance Verification & Calibration 87
6.2.1 Performance Verification Routine (*PC Classic only*) 88
6.3 Calibration (*PC Classic Plus Only*) 91
6.3.1 Calibration Routine 91
6.4 Printer Selection 96
Chapter 7: Data Management 99
7.1 Protecting Patient Data 99
7.2 Exporting and Importing Files 101
7.2.1 Exporting Files 101
7.2.2 Importing Files 102
7.3 Batch Reports 103
7.4 Calibration Review and Maintenance 104
7.5 Maintaining Users 105
7.6 Network Option (*PC Classic Plus Only*) 107
Chapter 8: Care and Maintenance 110

8.1 Maintenance of the PC Classic Flow Sensor 110
8.1.1 Removing the Easy Clean Core 110
8.1.2 Cleaning the Easy Clean Core 111
8.1.3 Installing the Easy Clean Core 111
8.2 Service 113
Appendices A-1
Definitions A-1
Normals Tables A-4
Diagnostic Interpretation A-9
Interpretation Table A-10
References A-10
Standards and Guidelines: A-10
Additional Resources: A-11
Spirometry Websites: A-12
Product List A-12
Accessories: A-12
Educational Products A-13

SPECIFICATIONS

MODELS

The PC Classic and the PC Classic Plus consist of a sensor handle and the Classic Windows™-based software. Together, these items make up the complete PC Classic system.

PC Classic: Consists of the Classic sensor handle and Classic software configured to measure and compute the following indices at minimum: FVC, SVC, FEV_1, FEV_3, FEV_6, FEV_1/FVC, FEV_1/FEV_6, PEF, FEF_{25-75}, FEF_{75-85}, FEF_{25}, FEF_{50}, FEF_{75}, $FEF_{200-1200}$, FIVC, PIF, FIF_{50}, FEF_{50}/FIF_{50}, and ET.

PC Classic Plus: The PC Classic Plus adds PRE/POST to the standard PC Classic test capabilities and allows the clinician to purchase MVV and/or Methacholine Challenge. It also allows addition of the network option.

NOTE!

The PC Classic can be upgraded to PC Classic Plus without the addition of new hardware.

The Classic software can be installed in any Windows™-based desktop or laptop computer that meets the minimum requirements described on the next page.

GENERAL

Weight / Size (sensor handle and cord only)	1.1 lbs. (0.5 kg) 8" h x 4" d x 2.8" w
Computer hardware requirements (minimum)	• 90 MHz Pentium class processor • 8 Mbytes RAM • 7 Mbytes available hard disc space • Compliance to applicable electromagnetic compatibility standards • Compliance to applicable electrical safety standards • SVGA (800X600 screen resolution or better) • Windows compatible printer • Available serial port
Operating System	Windows 95 or 98, Windows NT Work Station 4.0, Windows ME, Windows 2000 Professional and Windows XP.[1]
Hazardous / Flammable Environments	EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.
Mode of Operation	Rated for continuous operation

[1] Windows 95/98, Windows NT Workstation 4.0, Windows ME, Windows 2000 Professional and Windows XP Professional are registered trademarks of Microsoft Corporation, Redmond, Washington.

ELECTRICAL

Power	Derived from the RS-232 port.
Serial Port	RS-232C compliant
EMC	Compliant with Standard 60601-0, 1990 of the Electromagnetic Compatibility Directive

OPERATING

Meets or exceeds *Standards of Spirometry* requirements, 1994 update, American Thoracic Society, Medical Section of the American Lung Association.

Flow Ranges	-14.0 to 14.0 liters/second

ENVIRONMENTAL

Operating	17°C (63°F) to 40°C (104°F) 0 – 80% Relative Humidity
Storage Temperature	-18°C (0°F) to 50°C (122°F)
Humidity	0 – 80% Relative Humidity

NOTES

Chapter 1: *INTRODUCTION*

1.1 WELCOME

You have purchased a Spirometrics Medical Equipment Company PC Classic/Classic Plus spirometer for Windows™ [2]. The PC Classic/Classic Plus represents the newest technology in the medical equipment field. Its ease of operation and durability will provide years of service.

Spirometrics is committed to designing products that meet the highest standards of quality instrumentation for pulmonary function testing. We have designed the PC Classic/Classic Plus to take advantage of the latest developments in computers and software.

NOTE!
Federal law restricts this device to use by or on the order of a physician.

NOTE!
Before setting up, please complete the warranty card, enclosed at the end of this chapter, to ensure that your warranty rights are covered.

1.2 PRODUCT DIFFERENCES: PC CLASSIC VS. PC CLASSIC PLUS

The **PC Classic** is a monitoring device designed to be used in screening applications, e.g. early detection of Chronic Obstructive Pulmonary Disease (COPD). Spirometry is the only test available on the PC Classic.

[2] Windows™ is a registered trademark of Microsoft Corporation, Redmond, Washington.

The **PC Classic Plus** is a diagnostic device used in clinical applications, such as bronchodilator evaluation and provocation testing, that requires a very high standard of accuracy. The PC Classic Plus contains routines for calibrating the spirometer that are not available on the PC Classic. These calibration routines meet the 1994 American Thoracic Society (ATS) recommendations. Also, networking is only available with the PC Classic Plus.

The **PC Classic** can be upgraded to the **Classic Plus** at any time. For more information about the upgrade call our toll-free number: 1-800-767-0004.

1.3 WARRANTY

The **PC Classic/Classic Plus** is warranted for one year from delivery date as validated by the return of the warranty card or, if the warranty card is not returned, one year from the date of manufacture.

During the warranty period, any original parts and/or workmanship proven to be defective will be replaced or repaired at an authorized service center provided the equipment has been operated and maintained in accordance with the instructions contained in this manual. This warranty applies to the original user only and does not extend to any product or component that has been repaired or altered by anyone other than personnel authorized by Spirometrics. This warranty is in lieu of and excludes any warranty as to merchantability and all other warranties expressed or implied and do not cover consequential damages due to improper use or application of the product.

For the device warranty to be in effect, the warranty card packaged with this product must be returned to Spirometrics Medical Equipment Company for warranty registration. *Please take this time to fill out the postage-paid warranty card.* You may also register your warranty by calling 1-800-767-0004 or

faxing the information to 207-657-4123. For software license and warranty information, refer to the first 2 pages of this manual.

NOTE!

Computers, printers, and products not manufactured by Spirometrics are **not** covered under the one-year warranty. These products are covered under the manufacturers' warranties, which may vary. Please consult the appropriate user's manuals for further details.

NOTES

Chapter 2: *SAFETY*

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

2.1 INTENDED USE

The PC Classic and PC Classic Plus spirometers are intended for use with adult and pediatric patients for the diagnosis and monitoring of pulmonary disorders. The company disclaims responsibility for all other uses, and the user agrees to assume liability for damages resulting from non-intended use or operator error by the user or user's employees.

The PC Classic is not intended for use as a diagnostic instrument. Please upgrade to the PC Classic Plus for diagnostic capability.

The PC Classic is intended for use at a single facility or location. If the instrument is to be used at a different location other than its original setup location, the Classic software must be uninstalled, then re-installed to insure proper operation.

2.2 WARNINGS AND PRECAUTIONS

The following warnings and precautions must be heeded at all times:

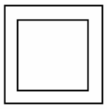
- Use a genuine Spirometrics filter/mouthpiece (Spiro-Filter) to ensure proper accuracy, reduce the risk of patient cross-contamination and to protect the internal sensor element. Replace the Spiro-Filter after each patient.

- Clean the Easy Clean Core regularly to insure the long-term stability and accuracy of the instrument. Please refer to Chapter 8: CARE AND MAINTENANCE for proper cleaning procedures. Do not attempt to clean the unit with abrasives or solvents. Do not autoclave any portion of the unit.
- Never immerse any component of the system in water or other liquids with the exception of the Easy Clean Core.
- Use only a desktop or laptop PC that adheres to the specifications listed in the Specifications section of this document.
- The PC Classic has a built-in operation verification feature to insure the operation of the system. Establishment of verification procedures and schedule are the responsibility of the user. The ATS 1994 spirometry recommendations and the American Association for Respiratory Care (AARC) 1996 Spirometry Clinical Practice Guideline provide guidance.
- The PC Classic Plus has built-in calibration capability. The 1994 ATS standard on spirometry recommends daily calibration of this instrument or more frequently as appropriate.
- Accurate and effective use of the PC Classic and PC Classic Plus depends on correct application of well established spirometry practices.
- Do not operate the unit in a flammable or explosive atmosphere.
- Insure that the Easy Clean Core is properly installed as described in Chapter 8: CARE AND MAINTENANCE.
- Do not drop the sensor handle. The PC Classic handle is a sensitive measurement device. Improper handling could affect the accuracy of its reported results.
- Do not disassemble sensor handle. There are no user-serviceable parts inside.

2.3 DISPOSAL

This instrument contains electronic circuitry and multiple plastics. Please dispose of properly at the end of useful life. Computer recycling facilities are capable of recycling this instrument.

2.4 SYMBOLS AND DEFINITIONS

Symbol	Definition	Spirometrics Notation
	Attention, consult accompanying documents	The specific directions in this manual and on the PC Classic handle must be observed.
	Dangerous voltage	The system must not be modified or serviced except by authorized personnel.
	Class II Equipment	
	Type BF Equipment	

NOTES

Chapter 3: *EQUIPMENT PREPARATION*

3.1 PREPARING FOR INSTALLATION

NOTE!
The PC Classic/Classic Plus is shipped in a box specifically designed to protect it during shipment. Keep the shipping box and packing materials in case you ever need to ship the unit for service or maintenance.

Common Windows tasks and uses should be familiar to the user before attempting to operate this program. Consult the Microsoft® Windows™ user's manual if this is not the case.[3]

3.1.1 INVENTORY

After unpacking your new PC Classic/Classic Plus, check each item against the following list:

1	Handle Assembly for PC Classic/Classic Plus
1	Coiled Cable
1	9-pin Adapter
1	Program CD
1	User's Manual & Warranty Card

[3] Windows™ and Microsoft® are registered trademarks of Microsoft Corporation, Redmond, Washington.

NOTE!

If anything is missing, immediately contact a Spirometrics inside sales representative:

- Phone: 207-657-6700 or 1-800-767-0004.
- E-mail: spiro@spirometrics.com

3.1.2 CONNECTING THE CLASSIC SENSOR

To connect the Classic Sensor, do the following:

1. Connect one end of the coiled cable to the outlet on the bottom of the Classic Sensor.
2. Connect the other end of the coiled cable to the telephone type connector of the 9-pin adapter.
3. Plug the 9 pin end of the adaptor into one of the serial ports (COM1–COM4) on the back of the host computer.

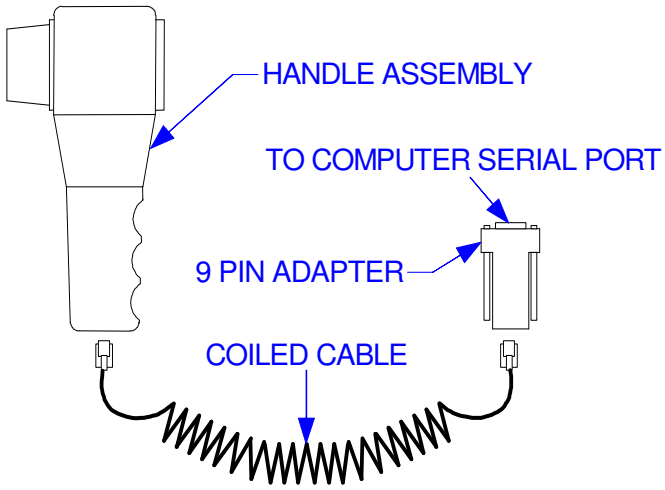


Figure 3-1: *Connection Diagram.*

NOTE!

If a 25-pin adapter (PN 15111F) is needed to connect your sensor to a COM port on your computer, call Inside Sales (207-657-6700 or 1-800-767-0004) to obtain one *or* buy a DB9 to DB25 adapter from a local computer supply house.

The PC Classic/Classic Plus for Windows is automatically set to the proper COM port by the Startup Wizard. The COM port can also be manually set by accessing the **Customization** option. See Section 6.1 CUSTOMIZATION, for details.

3.2 SOFTWARE INSTALLATION

If you purchased the computer from Spirometrics, the PC Classic/Classic Plus software will be loaded and configured on your computer. If you already have a computer or purchase one from a source other than Spirometrics, you will need to install the software.

To load the software, insert the CD into the CD drive. The program should load automatically. If not, do the following:

1. Click the **START** button.
2. Select **RUN**.
3. Select, or enter, ***<CD drive letter>:\setup.exe*** on the **Open** command line and click **OK**.
4. Follow the instructions in the PC Classic InstallShield Wizard.

NOTE!

When asked to confirm or change the program Destination Folder, Spirometrics recommends accepting the default destination. However if you wish to install this program software and data on a server or network location, please consult your network administrator.

3.2.1 INITIAL SETUP WIZARD

Run PC Classic for the first time by one of the following methods:

Double click on the newly created PC Classic shortcut icon on your desktop, or

Select **Programs** (**All Programs**), **Spirometrics**, **PC Classic v2.11**, **PC Classic** under the Windows **Start** menu.

The PC Classic Wizard takes over to complete the installation. The entire process takes only a couple of minutes.

The first five windows that you will see during installation serve three purposes:

- They tell the user what is happening.
- They verify that the sensor is properly connected.
- They allow you to set the report heading and ambient condition default parameters.

3.2.2 WELCOME WINDOW

The first window is a welcome message. Read the message, then click **Next** or press the **Enter** key to proceed.

Welcome to the
Spirometrics' PC-CLASSIC
modular spirometry system
This Wizard will help gather the information
we need in order to get you started.
Click the 'Next' Button to continue.....
Next

Figure 3-2: *Welcome Window.*

3.2.3 SENSOR FOUND WINDOW

The second window informs you that the sensor has been properly connected. If the sensor is not connected properly, check the back of your PC or laptop to make sure that the connection is okay as described in 3.1.2 Connecting the Classic Sensor. Follow the instructions in your PC owner's manual to ensure that your serial communications port is enabled.

When ready, click **Next** or press the **Enter** key to proceed.

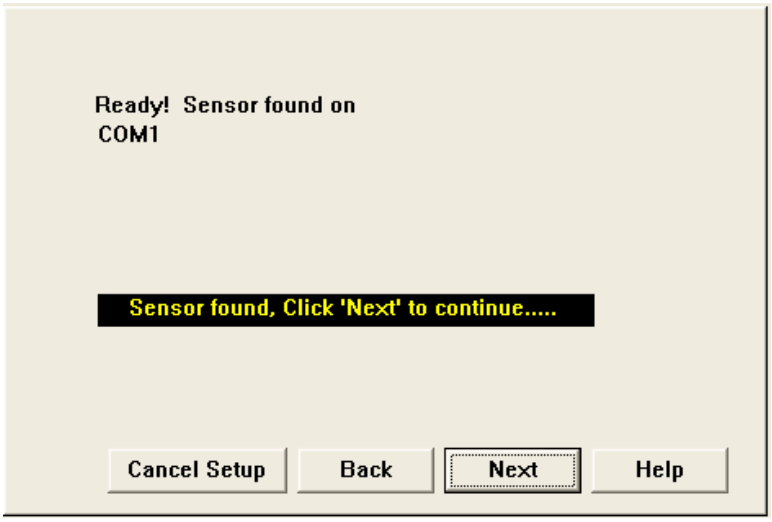


Figure 3-3: *Sensor Found Window.*

3.2.4 ADDRESS WINDOW

The third window asks you to input the name of the practice, clinic, or hospital that will be using the spirometer. This information will appear on all hard copy reports. There are four lines available for inputting the information. If you wish to complete or change this information at any time, refer to section 6.1.3 Report Setup in this manual which describes the appropriate customization procedure.

When ready, click **Next** to proceed.

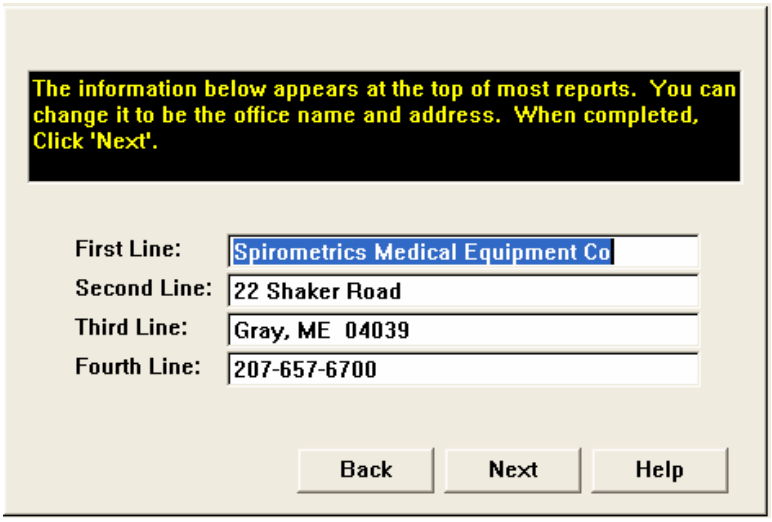


Figure 3-4: *Address Window.*

3.2.5 AMBIENT CONDITIONS WINDOW

The fourth window allows you to change the default ambient conditions. This data is used to calculate a correction factor called Body Temperature and Pressure Saturated (BTPS) that is applied to the lung volumes measured during patient testing. Gas volumes are reduced as they are exhaled from a warm body into a cooler room. The BTPS adjusts the lung volumes measured during testing so that they more accurately resemble conditions in the body. Ambient conditions should be accurately recorded each day testing is performed. This data can also be changed at anytime by accessing the **Customization** option. (See section 6.1.1 Software Customization.)

When ready, click **Next** to proceed.

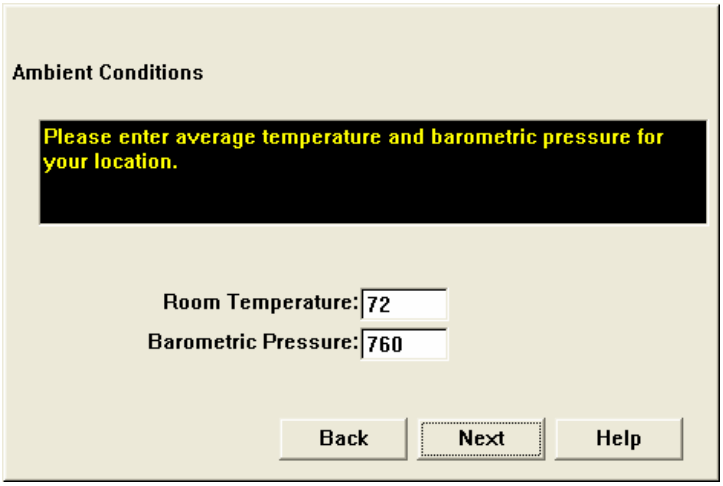


Figure 3-5: *Ambient Conditions Window.*

3.2.6 ACCESS CODES WINDOW

Enter unique activation codes in the **Access Codes Window** for the modules that you have purchased. You may have up to five license code entries. Please refer to the first page of this manual or your PC Classic software CD packaging for a list of license codes that you have purchased.

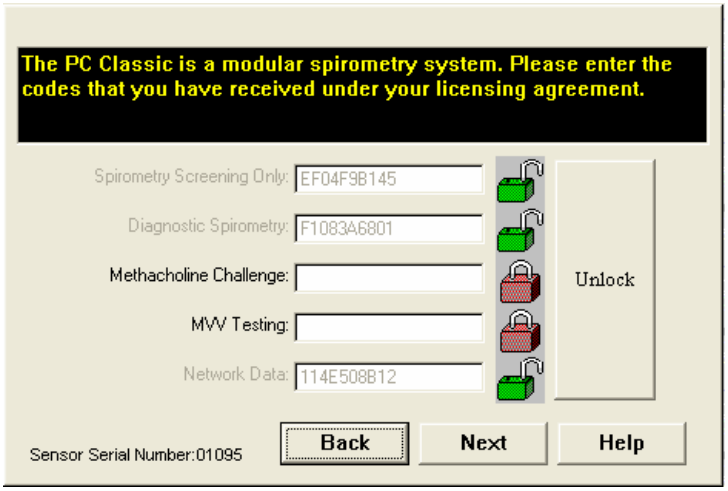


Figure 3-6: *Access Codes Window.*

- If you have purchased a PC Classic for screening only, enter only the first access code.
- If you have purchased the PC Classic Plus, enter the first two access codes.
- If you have purchased the Methacholine Challenge, Maximum Voluntary Ventilation (MVV), or Network Data options, enter those access codes in addition to the first two codes.

After entering each code in its appropriate box, click the **Unlock** button on the right. If the access code has been entered correctly, the lock icons will change from locked to unlocked. If at any time you choose to purchase additional license options, you may enter those license codes by accessing the **Customization** option as described in section 6.1.6 Licensing.

When ready, click **Next** to proceed.

3.2.7 ATTACHING THE 3-LITER SYRINGE

The next window to appear will depend upon whether you have purchased a PC Classic or a PC Classic Plus.

- If you have the PC Classic, you will see the **Performance Verification** window.
- If you have the PC Classic Plus, you will see the **Initial Calibration** window.

In both cases the 3-liter syringe should be connected to the sensor as shown.

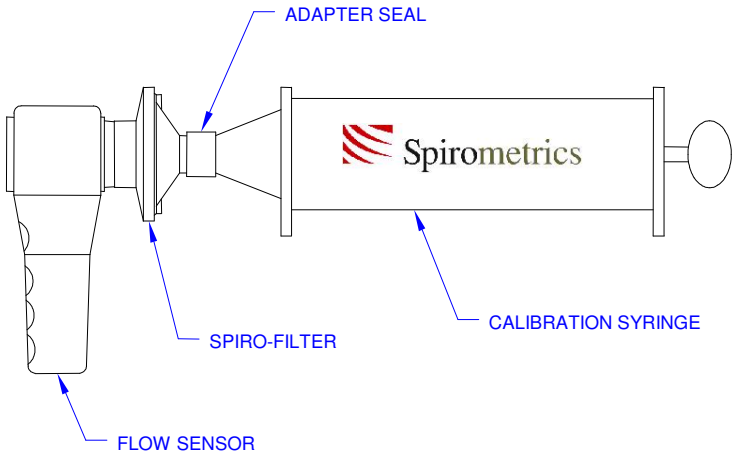


Figure 3-7: *Flow Sensor and 3-Liter Syringe.*

To connect the 3-liter syringe to the flow sensor, do the following:

1. Connect the adapter seal to the end of the 3-liter syringe.
2. Connect the flow sensor mouthpiece firmly to the 3-liter syringe.

Once the syringe is firmly connected, follow the installation routine for the software you have purchased, as described in the following sections.

3.2.8 PERFORMANCE VERIFICATION ROUTINE (*PC CLASSIC ONLY*)

If you purchased the PC Classic, the **Performance Verification** window will open after the correct access codes have been entered.

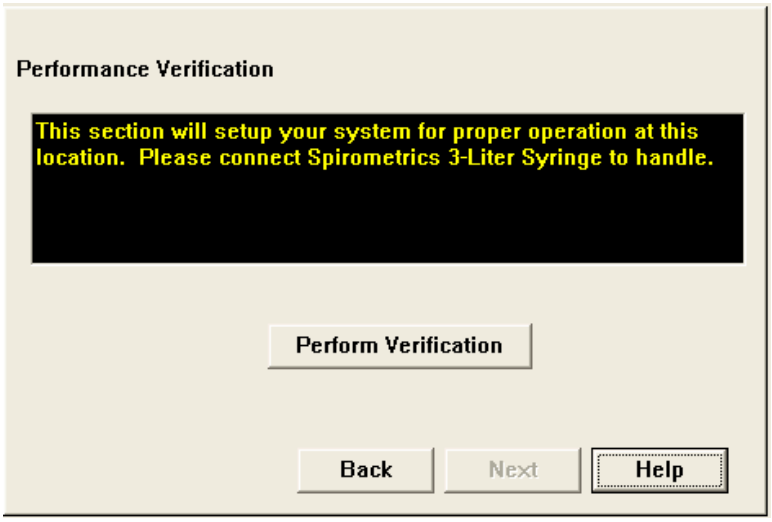

Performance Verification
This section will setup your system for proper operation at this location. Please connect Spirometrics 3-Liter Syringe to handle.
Perform Verification
Back
Next
Help

Figure 3-8: *Performance Verification window.*

The following steps describe how to complete the performance verification sequence:

1. Click the **Perform Verification** button. The **Prepare for Product Verification** window will appear.

NOTE!

A 3 liter syringe is required to perform initial calibration for the PC Classic / Classic Plus system.

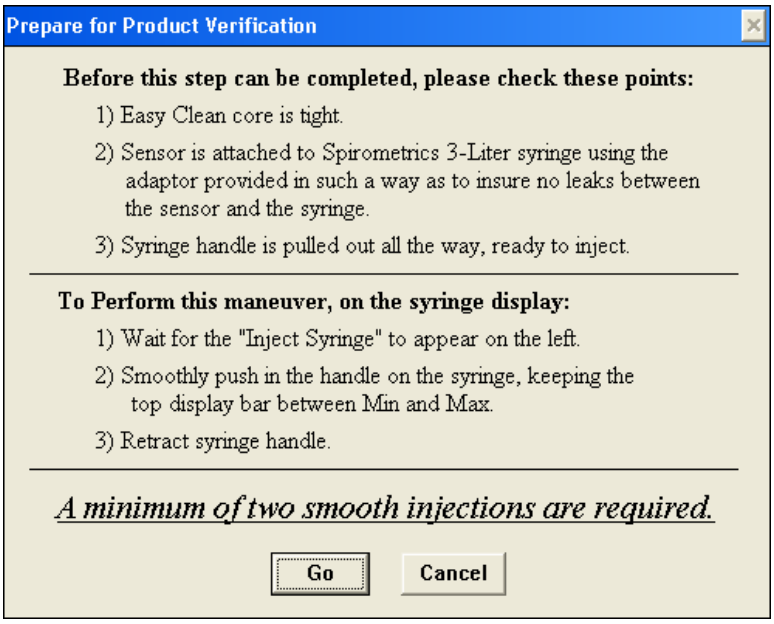

Prepare for Product Verification
Before this step can be completed, please check these points:
1) Easy Clean core is tight.
2) Sensor is attached to Spirometrics 3-Liter syringe using the adaptor provided in such a way as to insure no leaks between the sensor and the syringe.
3) Syringe handle is pulled out all the way, ready to inject.
To Perform this maneuver, on the syringe display:
1) Wait for the "Inject Syringe" to appear on the left.
2) Smoothly push in the handle on the syringe, keeping the top display bar between Min and Max.
3) Retract syringe handle.
A minimum of two smooth injections are required.
Go
Cancel

Figure 3-9: *Prepare for Performance Verification Window.*

2. Read the instructions carefully.
3. Pull the handle out to its farthest extent.
4. Click **Go** when ready to proceed.
5. A dialog box will appear instructing you to verify that the syringe is ready. Click **Ready** to continue.

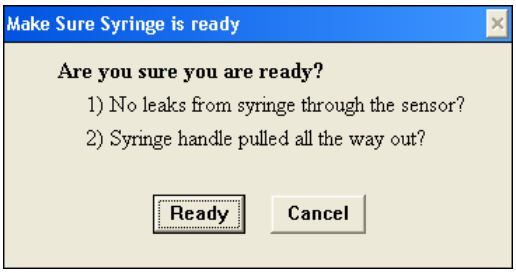

Make Sure Syringe is ready
Are you sure you are ready?
1) No leaks from syringe through the sensor?
2) Syringe handle pulled all the way out?
Ready
Cancel

Figure 3-10: *Syringe Ready Dialog Box.*

6. A full-screen display that shows the syringe injection will appear.

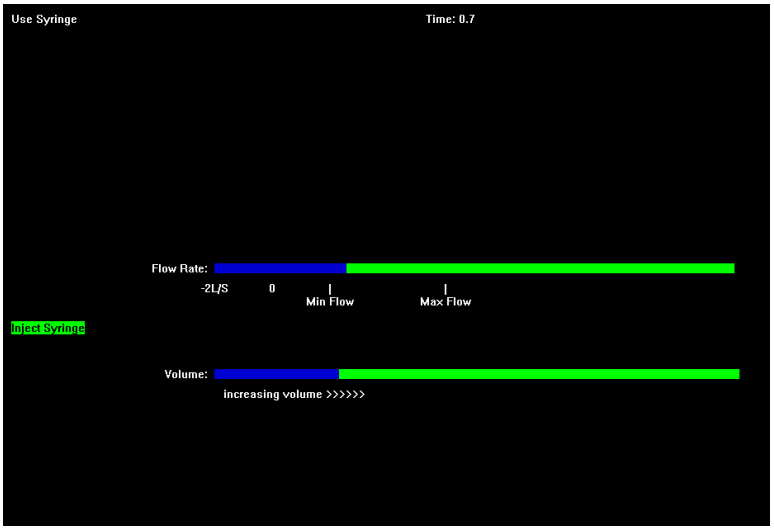


Figure 3-11: *Full-screen Display –Syringe Injection.*

7. Wait for the "Inject Syringe" command to appear on the left.
8. Push in the handle. Be sure to use a steady, continuous stroke in such a manner that the scroll bar remains between the "Min Flow" and "Max Flow" markers.

9. When done, immediately pull the handle back all the way to prepare for another injection.

10. If your injection was too fast or too slow, you will be given the opportunity to repeat the injection. If several failed injection attempts are made, a dialog box will appear instructing you to "**Keep Trying**".

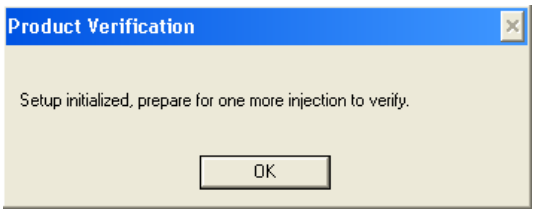


Figure 3-12: *Product Verification Dialog Box.*

11. After your first successful injection a dialog box will appear indicating that one more injection is required to verify the calibration. Repeat steps 5 through 10, following the on-screen prompts until a **Performance Verification Results** window appears reporting the measured volume. The measured result should be between 2.91 and 3.09.

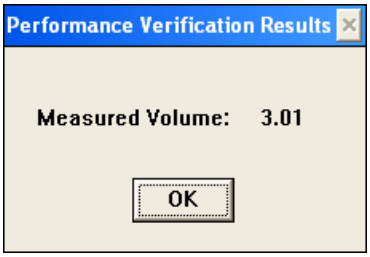


Figure 3-13: *Performance Verification Results.*

12. Upon completion of performance verification, the **Finished** window will appear. The system is ready for patient testing.

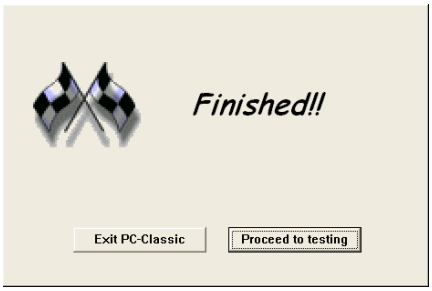


Figure 3-14: *Finished Window.*

Additional performance verifications may be performed at any time by selecting the **Performance Verification** option on the program window. See section 6.2 Performance Verification.

3.2.9 CALIBRATION (*PC CLASSIC PLUS ONLY*)

If you purchased the PC Classic Plus, the **Initial Calibration** window will open after the correct access codes have been entered.

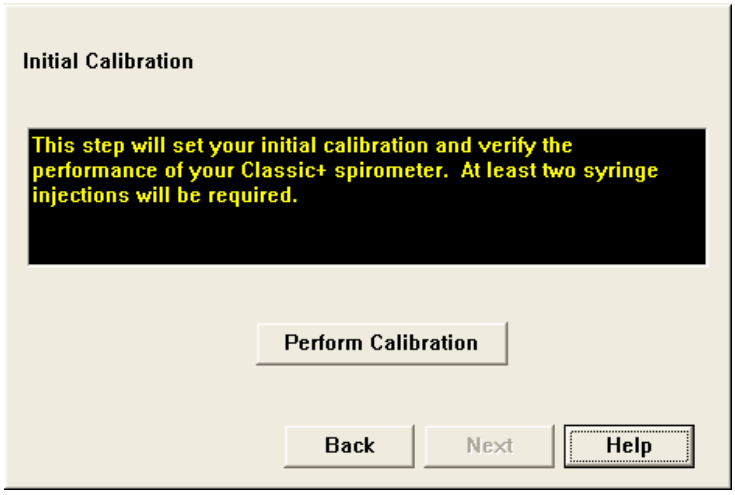

Initial Calibration
This step will set your initial calibration and verify the performance of your Classic+ spirometer. At least two syringe injections will be required.
Perform Calibration
Back
Next
Help

Figure 3-15: *Initial Calibration Window.*

The following steps describe how to complete the calibration sequence:

1. Click the **Perform Calibration** button. The **Calibration** dialog box will appear. It displays the syringe volume, set to a default value of 3 liters.

NOTE!
A 3 liter syringe is required to perform initial calibration for the PC Classic / Classic Plus system.

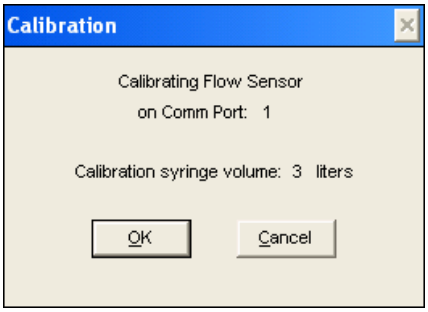


Figure 3-16: *Calibration Dialog Box.*

2. Click **OK** to proceed or **Cancel** to abort the calibration procedure.
3. If you selected **OK**, a second dialog box will appear with an instruction to "Hold SENSOR STEADY".

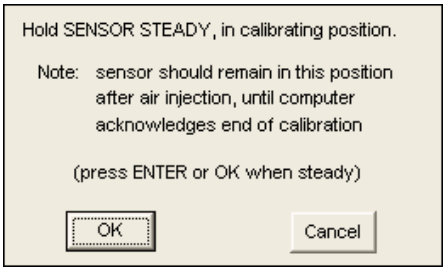

Hold SENSOR STEADY, in calibrating position.
Note: sensor should remain in this position
after air injection, until computer
acknowledges end of calibration
(press ENTER or OK when steady)
OK
Cancel

Figure 3-17: *Hold Sensor Steady Dialog Box.*

4. Pull the handle out to its farthest extent.
5. When ready, press **ENTER** or click **OK** to proceed. A full-screen display will appear.

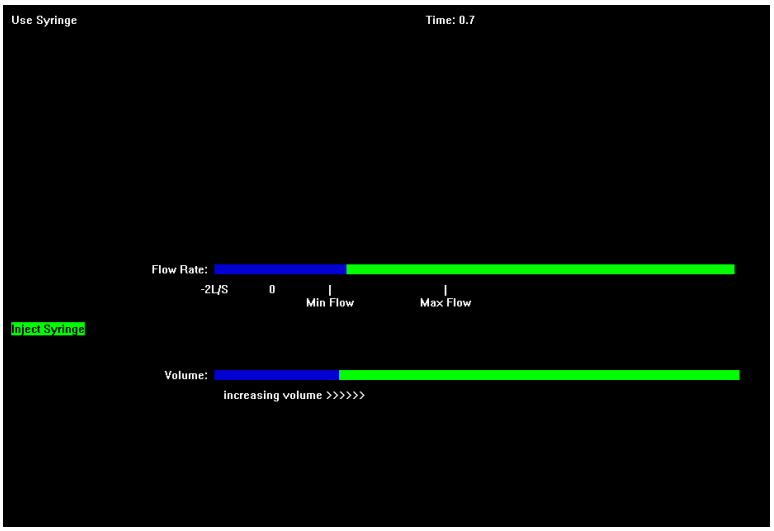


Figure 3-18: *Full-screen Display – Syringe Injection.*

6. Wait for the "Inject Syringe" command to appear on the left.
7. Push in the handle. Be sure to use a steady, continuous stroke in such a manner that the scroll bar remains between the "Min Flow" and "Max Flow" markers.
8. Upon successful injection, a **Verify Calibration** dialog box will appear. If your injection was too fast or too slow, the appropriate dialog box will appear instructing you to repeat the injection.

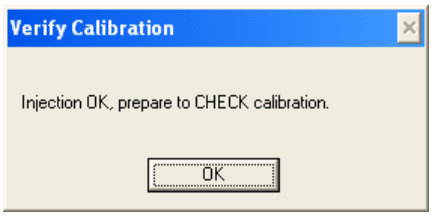


Figure 3-19: *Verify Calibration Dialog Box.*

9. Pull the handle back out to its farthest extent. Click **OK** to proceed.
10. Repeat steps 6 through 7.
11. Upon successful completion, a **Flow Calibration Results** window will appear, denoting that the calibration results are either "in agreement" or "not in agreement." The measured ATPS volume will be between **2.91 and 3.09**. You may print a copy of the calibration results or proceed to other calibration options. Calibration results are also saved in a data file. Calibration should be repeated if the results are "not in agreement".

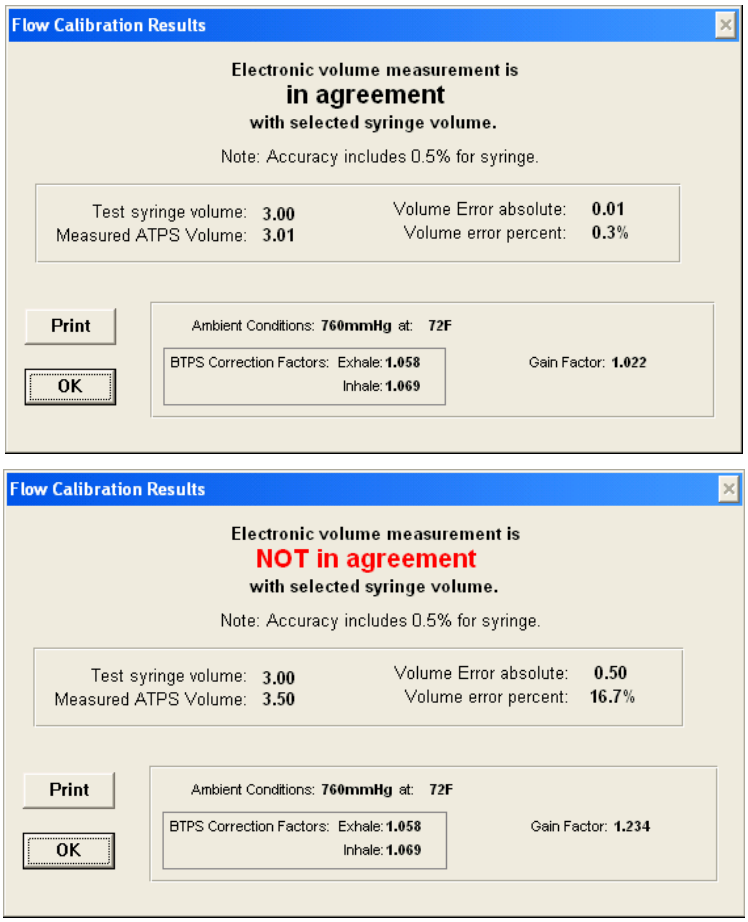


Figure 3-20: *Flow Calibration Results*.

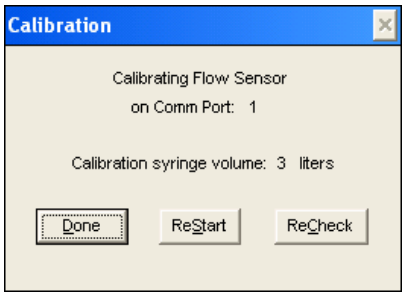


Figure 3-21: *Calibrating Flow Sensor Dialog Box.*

12. When ready to continue, click **OK**. A final calibration dialog box appears, offering three options:
    - Click **Done** to proceed to patient testing.
    - Click **ReStart** to repeat the calibration routine.
    - Click **ReCheck** to verify the calibration over a wide range of flow rates. See Section 6.3 Calibration (PC *Classic Plus Only)* for a review of the calibration and recheck procedures necessary to meet the 1994 ATS spirometry recommendations.

NOTE!

It is important to select the **ReCheck** option to verify the calibration over a wide range of flow rates. This option meets the ATS recommendations for calibration verification over a wide flow range. Proceed with this step as previously during the calibration routine. Each of three syringe injection routines must be completed separately by selecting **ReCheck**.

- Inject the syringe at a slow rate. (< 2 L/second)
- Inject the syringe at a medium rate. (4 to 6 L/second)
- Inject the syringe at a fast rate. (> 8 L/second)

The calibration window will appear after each injection. It should display "**in Agreement**" at all three flows.

13. If **Done** is selected a **Finished** window will appear indicating that the calibration process is complete.

Figure 3-22: *Finished Window.*

Additional calibrations may be performed at any time by selecting the **Calibration** option on the program window. See section 6.3 Calibration (PC *Classic Plus Only).*

NOTES

Chapter 4: *TEST PREPARATION*

4.1 PROCESSING PATIENT DATA

Patient information must be entered into the software before testing. Patient data is always accessed via **Browse Patient List** window.

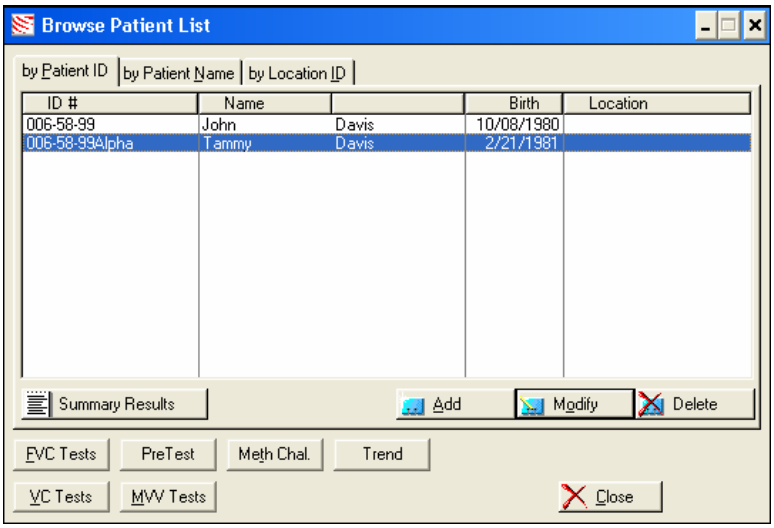


Figure 4-1: *Browse Patient List: (Test options will vary depending on whether you have the Classic or Classic Plus versions.)*

The following sections describe how to enter, retrieve, modify, and delete patient data.

4.1.1 ENTERING A NEW PATIENT

From the **Browse Patient List** window, select **Add**. The following window will appear:

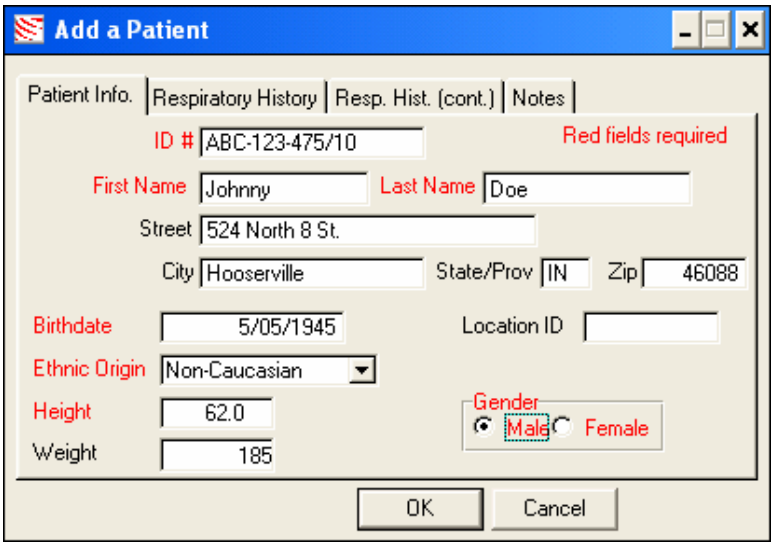


Figure 4-2: *Add a Patient: Patient Info.*

NOTE!

There are three ways of inputting and changing information in this software:

- Use the **Tab** key to move sequentially through each field.
- Use the **Enter** key to move from one *required* field to the next.
- Click the mouse to position the cursor in the desired field.

Enter patient information as follows:

ID#

Type the patient's identification number. This ID# may be any combination of letters and numbers but must be unique to each patient. The maximum number of characters is 20. *This field is **required**.*

First Name

Type the patient's first name. *This field is **required**.*

Last Name

Type the patient's last name. *This field is **required**.*

Street

Type the patient's street address. *This field is **optional**.*

City

Type the city in which the patient lives. *This field is **optional**.*

State/Prov

Type the state in which the patient lives. *This field is **optional**.*

Zip

Type the patient's zip code. *This field is **optional**.*

Birthdate

Type the patient's birth date, in mm/dd/yyyy format. *This field is **required**.*

Location ID

Enter a location ID number in this field. Maximum number of digits is 12. This field may be used to identify a specific test site or piece of equipment and is ***optional***. (It remains optional in network data.)

Ethnic Origin

Access the pull-down menu by clicking the ▼ button. Highlight one of the following choices: **Asian**, **Black**, **Caucasian**, **Hispanic**, and **Non-Caucasian**. After highlighting your selection, click the ▼ button. *This field is **required**.*

NOTE!

Selection of ethnic origin may impact the normal predicted results. Consult the Appendix to review the Normals Tables. The default reference for spirometry is NHANESIII.

Height

Enter the patient's measured height (without shoes) to the nearest one-half inch or centimeter: 40–89 is designated as inches; 90–250 is designated as centimeters. *This field is **required***

Weight

Enter the patient's weight in pounds or kilograms. (Units are set during customization. See Section 6.1 CUSTOMIZATION for specifics.) *This field is **optional***, but weight may impact the interpretation of the results.

Gender

Select the appropriate field for the patient. *This field is **required**.*

Predicted normal values are generally based on age, height, and gender. Review all entries for accuracy.

Press **ENTER** or click the **OK** button to accept the entries. The patient's first **Respiratory History** tab will then be displayed.

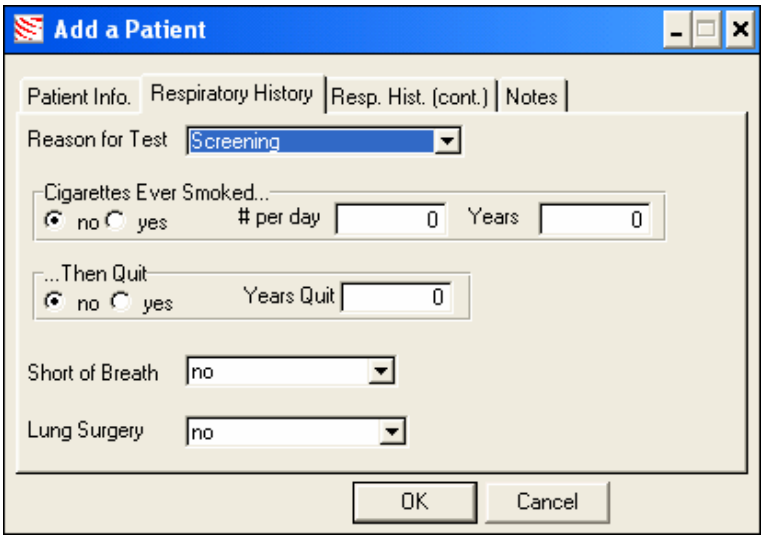


Figure 4-3: *Add a Patient: Respiratory History Tab.*

The **Respiratory History** tab contains default information. If the default entries are acceptable, press **Enter** or click the **OK** button to accept them**.**

If one or more of the default entries is not correct, you will have to enter information into the following fields:

Reason for Test

Access the pull-down menu by clicking the ▼ button. Highlight one of the following choices: **screening, asthma, COPD, lung fibrosis, pre-surgery** or **other**.

Cigarettes Ever Smoked

The default setting is **no** (if the patient has never smoked). Select **yes** if the patient has smoked.

 # per day

Enter the number of cigarettes the patient smokes each day.

Years

Enter the number of years that the patient has smoked.

Then Quit

The default setting is **no** (if the patient has not quit smoking or has never smoked). Select **yes** if the patient has quit smoking**.**

Years Quit

Enter the number of years since the patient stopped smoking. If the patient has not quit smoking, leave the default of **0** (zero).

Short of breath

The default setting is **no**. If it is not accurate, access the pull-down menu by clicking the ▼ button. Highlight one of the following alternate choices: **on stairs, walking,** or **at rest.**

Lung surgery

The default setting is **no**. If it is not accurate, access the pull-down menu by clicking the ▼ button. Highlight one of the following alternate choices: **one lung removed, lobectomy, biopsy,** or **other.**

After verifying that the information is correct, press **Enter** or click the **OK** button to accept the entries. The patient's **Resp. Hist. (cont.)** tab will then be displayed.

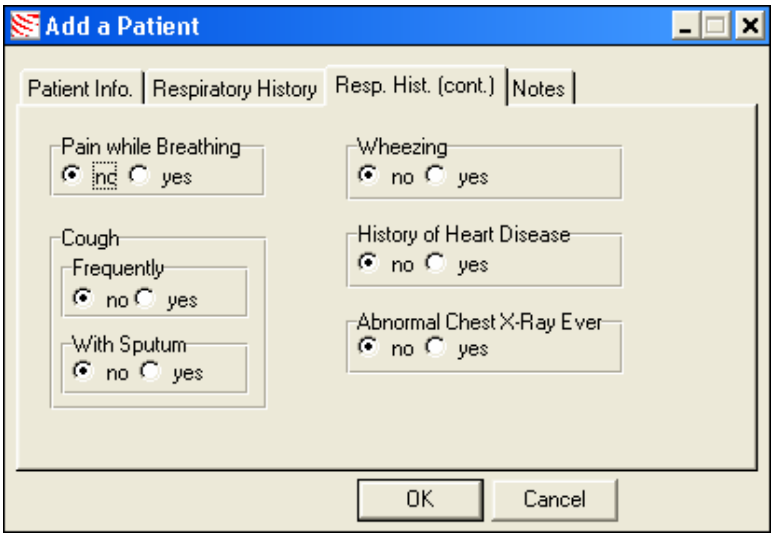


Figure 4-4: *Add a Patient: Respiratory History (Continued) Tab.*

The **Resp. Hist. (cont.)** tab contains default information. If the default entries are acceptable, press **Enter** or click the **OK** button to accept them**.**

If one or more of the default entries is not correct, you will have to enter information into the following fields:

Pain while Breathing

The default setting is **no** and is appropriate if the patient does not experience pain while breathing. Select **yes** if the patient experiences pain.

Cough [frequently]

The default setting is **no** and is appropriate if the patient does not cough frequently. Select **yes** if the patient coughs frequently.

[With Sputum]

The default setting is **no** and is appropriate if the patient coughs without producing sputum. Select **yes** if the patient produces sputum while coughing.

Wheezing

The default setting is **no** and is appropriate if the patient does not wheeze. Select **yes** if the patient wheezes.

History of Heart Disease

The default setting is **no** and is appropriate if the patient does not have a history of heart disease. Select **yes**, or click on the word **yes,** if the patient has a history of heart disease.

Abnormal Chest X-ray

The default setting is **no** and is appropriate if the patient has never had an abnormal chest x-ray. Select **yes** if the patient has had an abnormal chest x-ray.

The **Notes** tab contains a blank page to enter additional pre-test information. An example of information to include is medications, dose, frequency, time last taken, and delivery method. Information entered in the **Notes** tab is NOT printed on the report summary, but continues to be available in the patient's file.

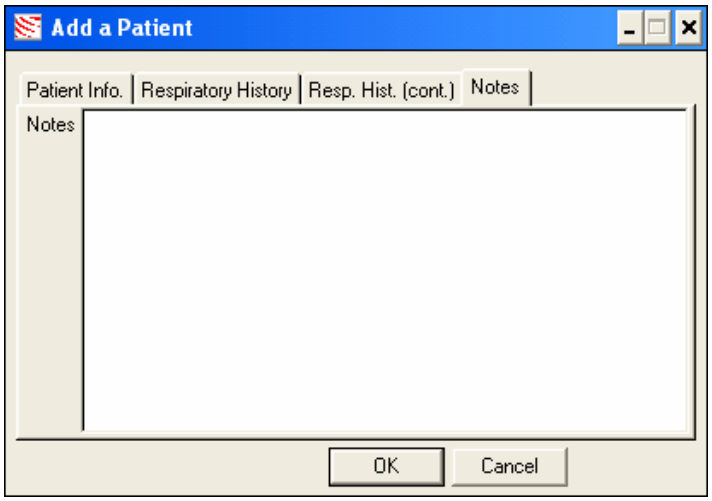


Figure 4-5: *Add a Patient: Notes Tab.*

After verifying that the information is correct, press **ENTER** or click the **OK** button to accept the entries.

The patient record has now been created. To begin testing, refer to Chapter 5: TESTING, in this manual.

4.1.2 RETRIEVING AND MODIFYING PATIENT INFORMATION

If you have tested a patient previously and the information is already stored in the system, you can access the patient's data by entering his or her ID number, Last Name, or Location ID at the **Browse Patient List** window.

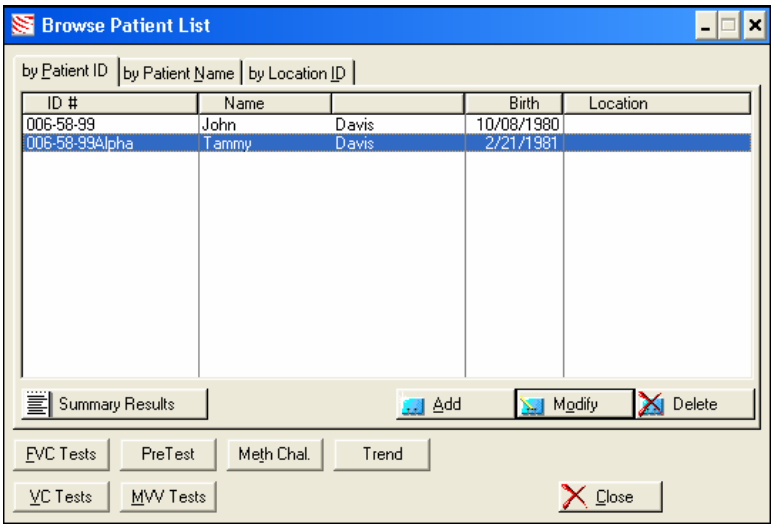


Figure 4-6: *Browse Patient List: (Test options will vary depending on whether you have the Classic or Classic Plus version.)*

To locate a patient's file, do **one** of the following:

- To locate the patient by **ID#**, click the **by Patient ID** tab. Enter the first digit or letter of the patient ID# and use the scrollbar or the arrow keys to scroll through the patient listing.
- To locate the patient by **Name**, click the by **Patient Name** tab. Enter the first letter of the patient's last name and use the scrollbar or the arrow keys to scroll through the patient listing.
- To locate a patient by **Location ID**, click the by **Location ID** tab. Enter the first digit or letter of the location and use the scrollbar or the arrow keys to scroll through the patient listing.

If you need to change patient information accessed through any of these methods, do the following:

1. Highlight the specific patient.

2. Click **Modify**.
3. Enter any necessary change(s) in each tab.
4. After all changes are made, press **Enter** or click the **OK** button to save immediately.

The updated information will be stored as part of the patient's record.

4.1.3 DELETING PATIENT INFORMATION

CAUTION: Deleting a patient from the system also deletes all associated records. This is not reversible.

To delete a patient from the system, do the following:

1. Locate the patient you want to delete.
2. Press the **Delete** key, or click the **Delete** button. The following **Confirm Delete** dialog box will appear:

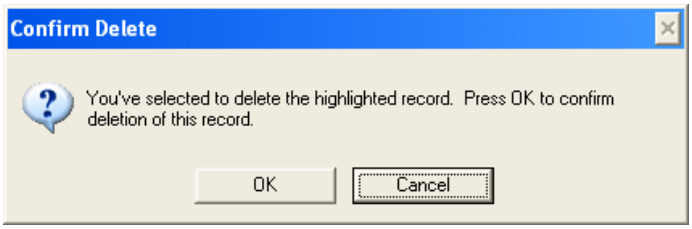


Figure 4-7: *Confirm Delete Dialog Box.*

3. Click the **OK** button to delete the selected patient record. Click the **Cancel** button or press the **Esc** key to abort the deletion of the patient record.

NOTES

Chapter 5: *TESTING*

This chapter describes how to perform the various tests available to users of both the PC Classic and the PC Classic Plus.

After entering information for a new patient or selecting an existing patient, select the test to be preformed by clicking on the appropriate test button (**Pre-Test (for training), FVC Tests, VC Tests, Post-Bronchodilator Tests, MVV Tests,** or **Methacholine Challenge Tests**). Each of these menu options is described in detail in this chapter. Options will vary depending upon available modules.

NOTE!

In its 1994 update to Standards of Spirometry, the American Thoracic Society (ATS) recommends that a minimum of three acceptable Forced Vital Capacity (FVC) tests be performed. Acceptability criteria are defined in the 1994 update. After three acceptable trials are performed, at least two trials should meet the reproducibility criteria. The limits require the two highest acceptable FVC and FEV1 measurements to agree within 200 mLs. To help the clinician achieve this reproducibility target, we have included a short routine in the PC Classic Plus called Pre-Test that can be done prior to the FVC tests.

5.1 OPTIONAL PRE-TEST TRAINING (*PC CLASSIC PLUS ONLY*)

For the pre-test, the patient takes several deep breaths through the spirometer. The results are compared to the patient's predicted inspiratory capacity (IC). This procedure provides two benefits: first, it maximizes and stabilizes the lungs' resting position. This is important because many patients, particularly those with sedentary lifestyles, will exhibit some degree of

atelectasis, i.e., collapsed alveoli. The pre-test will eliminate a source of variability and enhance the achievement of reproducible maneuvers. Second, the pre-test helps the patient acclimate to the surroundings, gain confidence in the clinician's instructions, perform the first half of the test with the spirometer, and contribute to an overall better testing experience.

To perform a Pre-Test, do the following:

1. From the **Browse Patient List** window, click the **PRE-test** button. The **PRE-Tests** window will open.

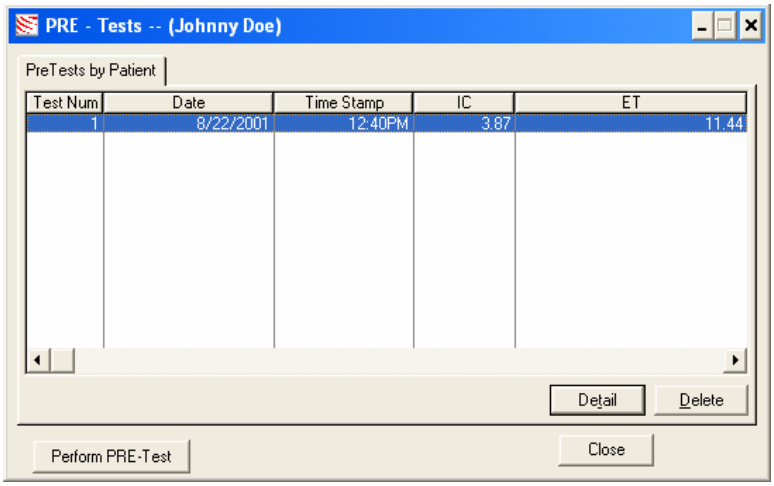


Figure 5-1: *PRE-Tests Window.*

2. Click the **Perform PRE-Test** button. Initially, the HOLD SENSOR STEADY box will appear. Click **OK**. A full-screen display will appear with a graduated scale and an arrow indicating the predicted Inspiratory Capacity (IC).

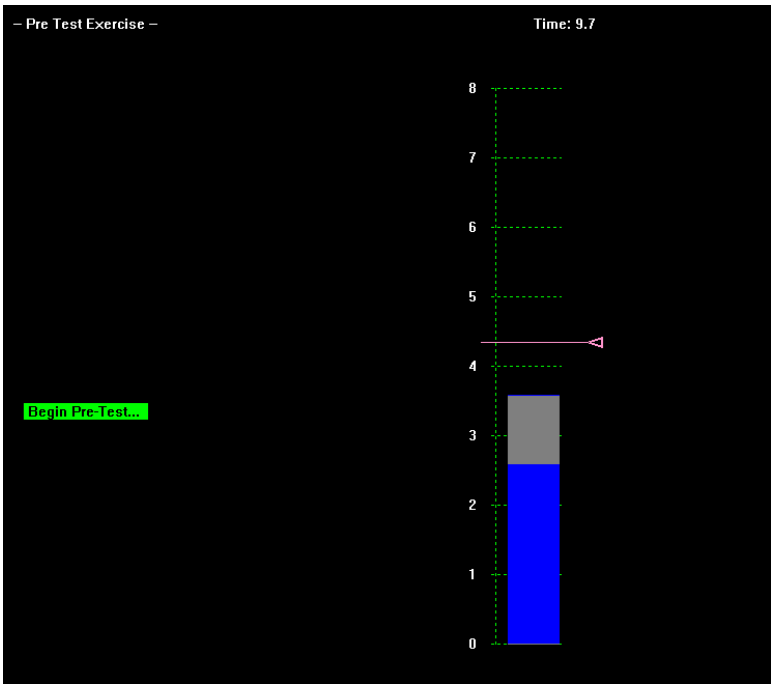


Figure 5-2: *Full-screen Display – PRE Test.*

3. Instruct the patient to place the sensor into his/her mouth, making sure to keep a tight seal.
4. Ask the patient to breathe quietly and, when ready, instruct the patient to inhale maximally. The display will show a bar moving up as the patient inhales.
5. After full inhalation is achieved, instruct the patient to exhale passively to the resting position.
6. Click the **Detail** button on each highlighted Test Number. A result window will appear showing the measured, predicted, percent predicted IC value and variance, in liters.

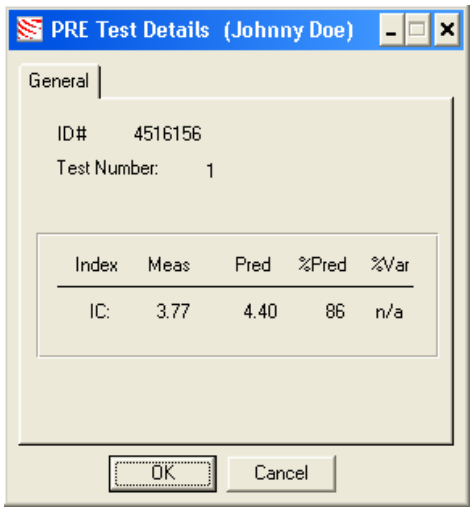


Figure 5-3: *PRE Test Details Display*.

7. Repeat the procedure until a maximal value for IC is achieved.
8. Close the IC results window and return to the **PRE-Tests, Browse Patient List** window to begin FVC testing.

5.2 FVC TEST

This **Forced Vital Capacity (FVC) Test** applies to both the PC Classic and the PC Classic Plus programs. To perform an FVC test, do the following:

1. Click the **FVC Test** button. The **FVC Tests** window will display the tests in descending order from the newest to the oldest.

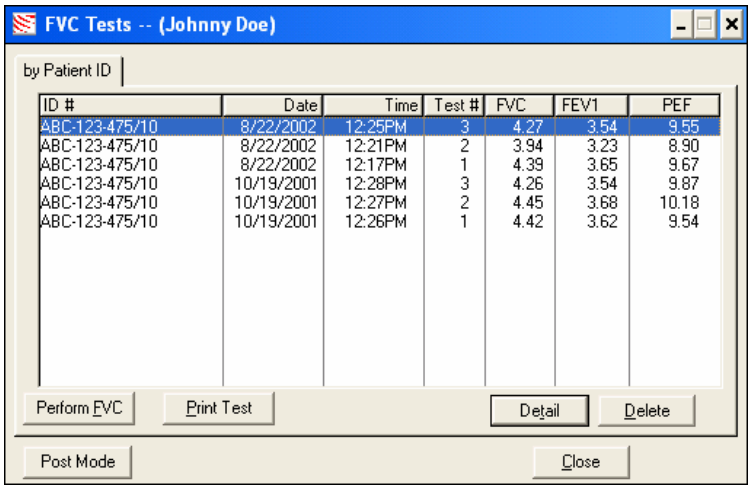


Figure 5-4: *FVC Tests Window.*

2. Instruct the patient how to perform the FVC maneuver and demonstrate the procedure to the patient. Coach the patient to breathe in as deeply as possible, place the mouthpiece in their mouth with the tongue placed under the mouthpiece, blow out as hard and as fast as possible, and breathe in as deeply as possible. Explain that nose clips will also be used.

NOTE!

Insert a new Spiro-Filter on to the flow sensor if this is a new patient.

3. Click the **Perform FVC** button to open the FVC test mode window.

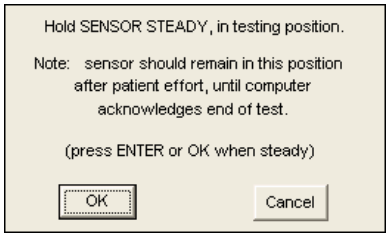

Hold SENSOR STEADY, in testing position.
Note: sensor should remain in this position after patient effort, until computer acknowledges end of test.
(press ENTER or OK when steady)
OK
Cancel

Figure 5-5: *Sensor Steady Warning.*

4. Hold the sensor steady in the testing position and click the **OK** button or press the **Enter** key when ready.

NOTE!
Clicking the **Cancel** button returns to the FVC Tests window.

NOTE!
The sensor's zero-point is being established and is not ready until the ***Begin FVC*** message is displayed.

5. Although a full loop (both inhalation and exhalation) is preferred and provides the most complete information, exhalation only can be obtained:

    a. When performing the complete loop, after the patient has reached a one-second plateau on the exhalation effort, he/she must forcefully begin the inhalation until full inspiration is achieved.

    b. If the full loop is not desired, the patient should continue to hold the sensor steady as the computer detects the end of the test. Moving the sensor may falsely record as patient effort.

6. The flow volume loop graph will appear on-screen and testing may begin.

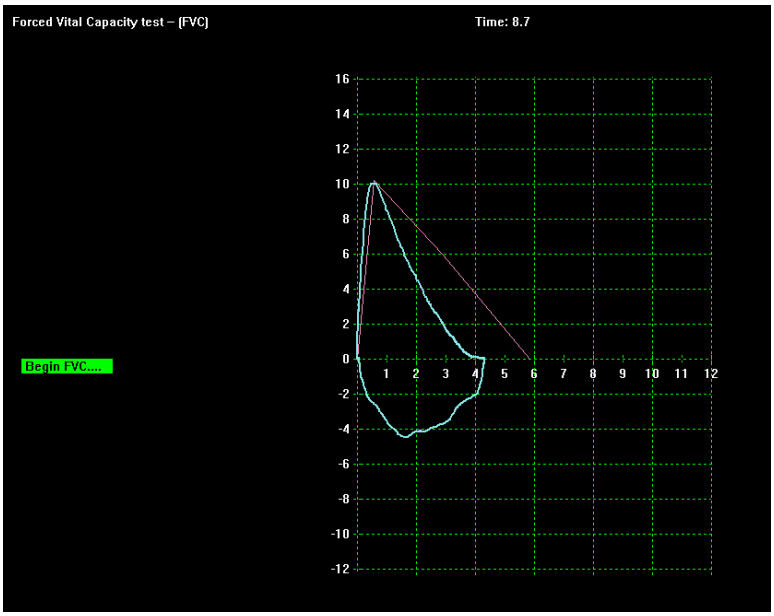


Figure 5-6: *Sample Flow Volume Loop Graph.*

NOTE!

When the necessary predicted normal values are available in the selected normals table, the graphs will contain a predicted curve. See the section 6.1.1 Software Customization and the Normals Tables section of the Appendix for more information.

7. Place nose clips on the patient and instruct in the following manner:

   a. "Breathe in as deeply as possible; then place your mouth securely around the mouthpiece with your tongue under the mouthpiece."

b. "Blow out as hard and fast as possible until I ask you to breathe in as deeply as possible again. Your mouth will still be on the mouthpiece, when you breathe in deeply the second time. Even if it feels like you have all the air out of your lungs, keep squeezing the air out until I ask you to breathe in deeply."

NOTE!

If only the exhale maneuver is to be performed, the sensor must be held steady until the end of test is determined (the software will wait five [5] seconds from the beginning of the plateau for the beginning of the inhalation to begin). A short inhale will immediately trigger the end of test.

8. Instruct the patient to begin the procedure whenever he or she is ready.

   As the patient exhales, the effort is being displayed on-screen. This display is used as an incentive for the patient to blow as hard, fast, and completely as possible and as feedback to the clinician as to how well the test is being performed. It is important to observe a sharp immediate peak at the beginning of the test. (The FV Loop incentive graph is the default setting. Refer to Section 6.1.1 SOFTWARE CUSTOMIZATION, to change the incentive display).

9. Once the patient has completed the maneuver, the following message window will appear on-screen:

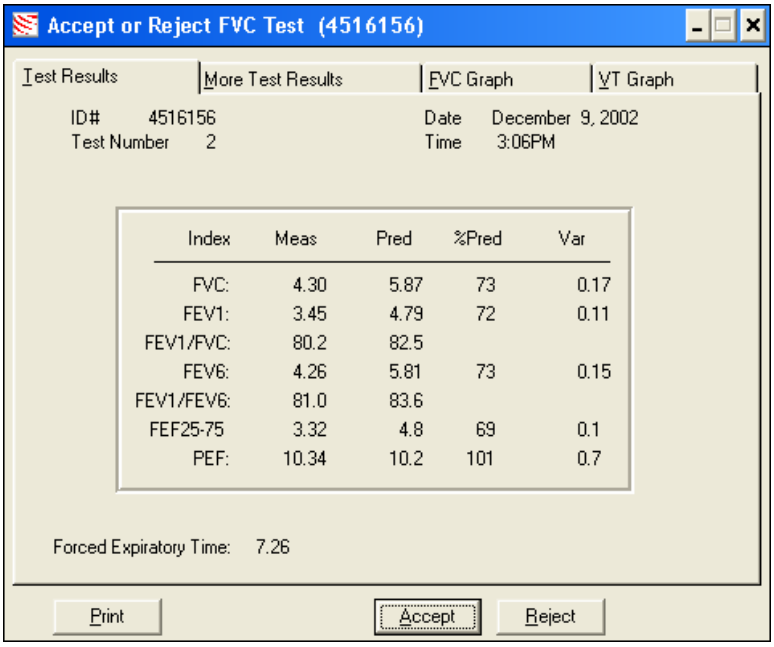


Figure 5-7: *Test Results Tab.*

NOTE!

The results in the **Var** column under the **Test Results** tab will appear as **n/a** if only one test has been performed.

NOTE!

You may print the current test by clicking the **Print** button, **Accept** the test and return to the **FVC Test** window, or **Reject** the test as unacceptable.

10. You may review all or any of the tabs prior to accepting, rejecting or printing the test. To do so, click on one of the following:
    - **More Test Results** displays additional indices.
    - **FVC Graph** displays the Flow-Volume Loop.
    - **VT Graph** displays the Volume-Time Graph.
11. Click **Accept** to accept the test or **Reject** to reject the test just performed.

    The effort was "acceptable" if the patient met all of the following criteria:
    - Started with a full inspiration to Total Lung Capacity (TLC)
    - Exhaled with an immediate, fast start (back extrapolation less than 5% of the FVC or 150 mL, whichever is greater)
    - Exhaled with maximal effort (observed on the peak flow)
    - Continued smooth continuous exhalation for at least 6 seconds or until there is no change in volume for one-second on the volume-time curve
    - No coughing in the first second
    - Inhaled maximally after the expiration

    Errors are also displayed on the Test Results tab to assist in re-instructing the patient.
12. Click **Perform FVC** to perform another FVC test.
13. When testing is complete, click **Close** to return to the **Browse Patient List** window. You may then:
    - Select a different type of test for the patient
    - Generate a summary report for the patient
    - Select a previous patient
    - Enter a new patient
    - Modify a patient's biographical information
    - Delete a patient's record.

5.2.1 WARNING MESSAGES

The following warning messages may appear:

- **Test Too Short – Expiratory Time < 6.0 Seconds** displays if the patient exhales for less than six seconds.
- **Slow Start – Extrapolated Volume > 5% of FVC** displays if the patient has a slow start to the test.
- **Early Termination – No Plateau in VT** displays if a one-second (1) plateau was not reached prior to the conclusion of the exhalation maneuver.

5.3 VC TEST

This test applies to both the PC Classic as well as the PC Classic Plus software. In patients with severe obstructive lung disease, the Forced Vital Capacity (FVC) may be reduced due to increased airway resistance or a loss of elastic recoil that results in early closure of the airways and gas trapping. Exhaling at much slower flow rates may allow the patient to more fully empty the lungs. A higher value for VC (Slow Vital Capacity) relative to the FVC may help rule out a combined obstructive/restrictive disorder, but static lung volumes must be measured for a definitive answer.

The difference between the FVC and VC measurements may estimate how much air is trapped in the lungs during a forced expiration.

To administer the test, perform the following steps:

NOTE!
Insert a new Spiro-Filter on to the flow sensor if this is a new patient.

1. Click the **VC Tests** button. The **VC Tests** window will display the tests in descending order from the newest to the oldest.

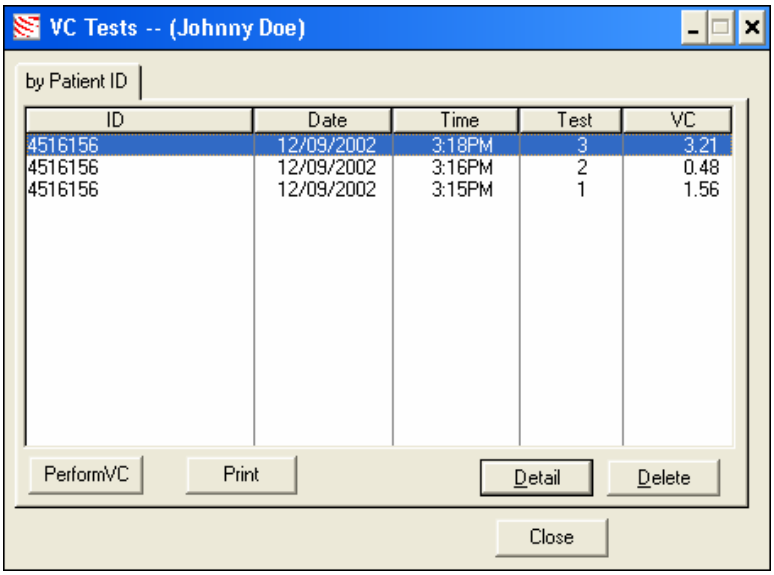


Figure 5-8: *VC Tests*.

2. The patient should be instructed to breathe in as deeply and completely as possible and then blow all of the air out slowly and completely.
3. Click the **PerformVC** button.
4. When the sensor is in the testing position, click **OK.**

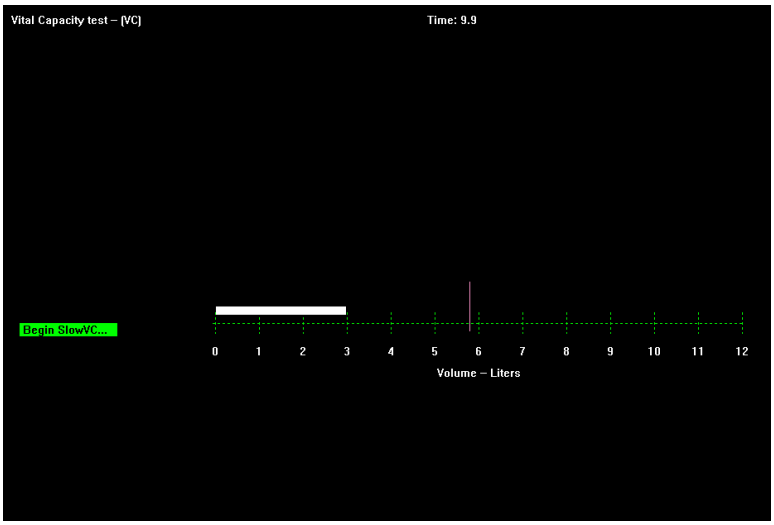


Figure 5-9: *Vital Capacity Test Graph*.

5. When the message **Begin SlowVC...** appears on-screen the zero-point has been established and the system is ready to begin the test.
6. Place nose clips on the patient and instruct the patient to do the following:
   a. "Breathe in as deeply as possible...place your mouth tightly around the mouthpiece with your tongue under the mouthpiece."
   b. "Blow all of the air out of your lungs slowly until I ask you to stop."
7. Once the maneuver is complete, the following window will appear:

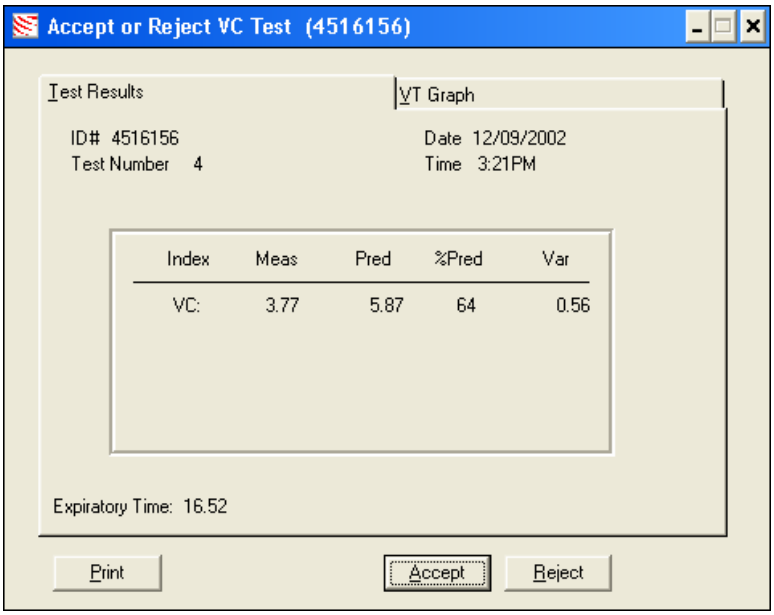


Figure 5-10: *Accept or Reject VC Test Window.*

Options on the Accept or Reject VC Test window are:

Test Results tab

This is the default window displayed after the test results are processed.

VT Graph tab

For review of the volume time curve created from the VC. This is only viewable at the initial accept / reject window. Once the test has been accepted, and the details are recalled for viewing, the volume time curve is no longer available for the VC test.

Print:

Prints a page report with the test results.

Accept

This choice indicates that the test was acceptable and returns to the Browse the VC Tests File window.

Reject

This choice indicates that the test was unacceptable.

The VC effort was "acceptable" if the patient:

- put forth a good effort
- inhaled completely
- exhaled completely and
- exhaled smoothly. (NO COUGHING!)

If you have completed testing this patient for VC, close the **VC Tests** window by either clicking the **Close** button or pressing the **Esc** key. This will return you to the **Browse Patient List** window.

5.4 POST-BRONCHODILATOR TESTING (*PC CLASSIC PLUS ONLY*)

If you would like to perform post-bronchodilator testing, there are two ways to enter post-bronchodilator testing mode.

NOTE!
The ATS and AARC have established recommendations for the administration of the bronchodilator and post-testing procedures.

5.4.1 METHOD 1:

If you have performed FVC tests on a patient and you have not closed the **FVC Tests** window for that patient, do the following from the **FVC Tests** window:

1. Click **Post Mode** button. The following window will appear:

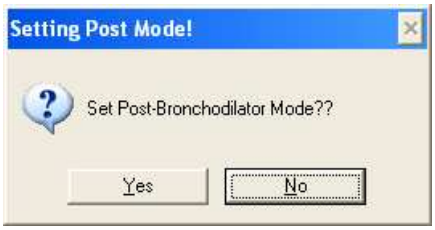


Figure 5-11: Setting *Post Mode Window*.

2. Click **Yes** if all pre-bronchodilator testing is complete and to set the patient for Post Mode. A dialog box will appear instructing you to administer a bronchodilator. Click **OK** to proceed. The **FVC Tests** window will appear with a title bar that reads: **FVC Tests - (patient name) [Post-Bronchodilator Testing]**. The **Post Mode** button will now be grayed out.

NOTE!

Once Post Mode is set for a patient on a particular day, it is **NOT POSSIBLE** to exit the post mode until the next day.

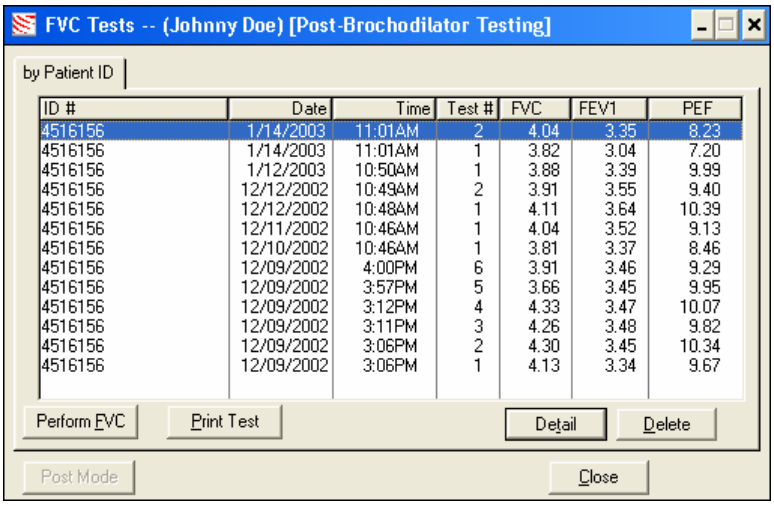


Figure 5-12: FVC Tests *Post Mode Window*.

3. Perform post mode FVC tests by clicking on the **Perform FVC** button.

4. To view post mode test details, select the desired test and click on the **Detail** button. A **FVC Test Details** window will appear. If the test was performed in the post-bronchodilator mode, a note at the bottom right of the detail window will indicate: **Post Mode Test**. If the test was performed prior to entering the post-bronchodilator mode, there will be no message at the lower right area of the detail window.

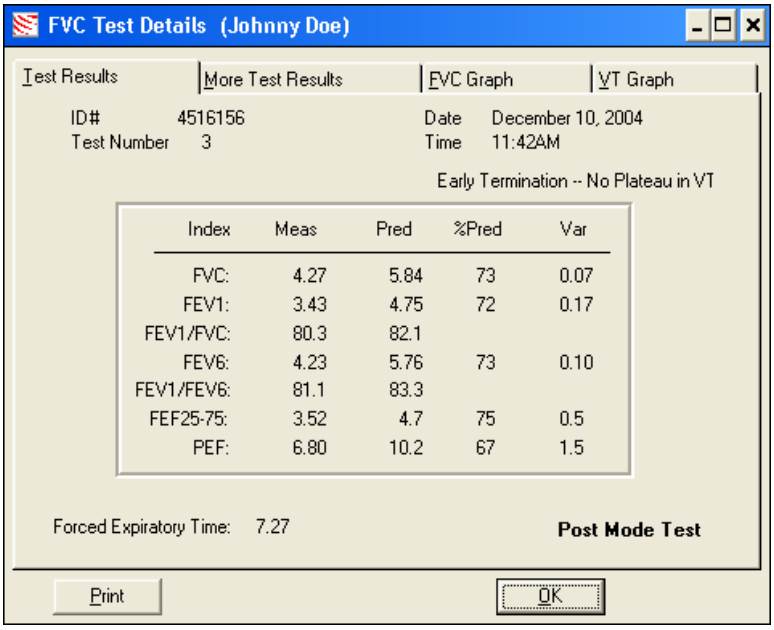


Figure 5-13: Bronchodilator Test Results in Details Window.

NOTE!

The 1991 ATS recommendations for interpretation of spirometry discuss limits for an acceptable response.

5. To view a testing report close the **FVC Tests** window and click on the **Summary Results** button in the **Browse Patient List** window. Post-bronchodilator results appear in a separate column on the test report, and a percent change from pre-bronchodilator results is also given.

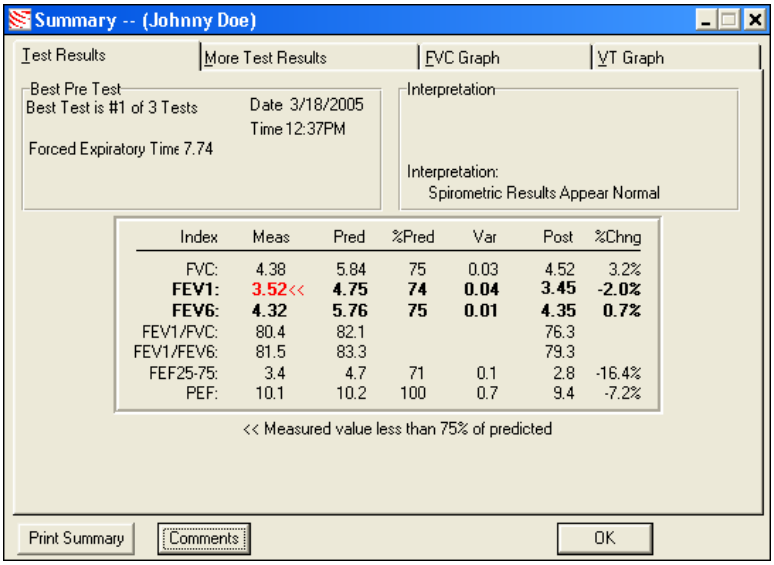

Summary -- (Johnny Doe)
Test Results
More Test Results
FVC Graph
VT Graph
Best Pre Test
Best Test is #1 of 3 Tests
Date 3/18/2005
Time 12:37PM
Forced Expiratory Time 7.74
Interpretation
Interpretation:
Spirometric Results Appear Normal
Index Meas Pred %Pred Var Post %Chng
FVC: 4.38 5.84 75 0.03 4.52 3.2%
FEV1: 3.52<< 4.75 74 0.04 3.45 -2.0%
FEV6: 4.32 5.76 75 0.01 4.35 0.7%
FEV1/FVC: 80.4 82.1 76.3
FEV1/FEV6: 81.5 83.3 79.3
FEF25-75: 3.4 4.7 71 0.1 2.8 -16.4%
PEF: 10.1 10.2 100 0.7 9.4 -7.2%
<< Measured value less than 75% of predicted
Print Summary
Comments
OK

Figure 5-14: Bronchodilator Test Results in Summary Window.

5.4.2 METHOD 2:

After administering a bronchodilator to a particular patient, you may wish to perform other tests on other patients. If you have returned to the **Browse Patient List** window after performing FVC tests and before you have entered the post mode by clicking on the **Post Mode** button, you may enter the post bronchodilator testing mode by doing the following from the **Browse Patient List** window:

1. Highlight the patient's name.

2. Click the **FVC Tests** button.
3. If you have already performed testing on this patient earlier in the day, you will be prompted to set post-bronchodilator mode, click **Yes** if all pre-bronchodilator testing is complete. If all pre-bronchodilator testing is not complete, click **No** and complete pre-bronchodilator testing before proceeding to post-bronchodilator testing.

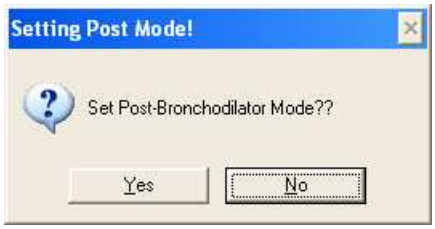


Figure 5-15: *Setting Post-bronchodilator Mode Window.*

NOTE!

Once Post Mode is set for a patient on a particular day, it is **NOT POSSIBLE** to exit the post mode until the next day.

4. You will not be prompted to administer a bronchodilator when using this method. Administer the bronchodilator if you have not already done so.

NOTE!

If you have not done testing on this patient earlier in the day and you click on the Post Mode button, you will see a dialog box instructing you to perform pre-bronchodilator testing. Click OK to return to the FVC Tests window.

5. Perform FVC tests according to steps 3 through 5 in section 5.4.1 Method 1: above.

5.5 MVV TEST (*PC CLASSIC PLUS ONLY*)

The Maximal Voluntary Ventilation (MVV) is a non-specific indicator of respiratory system dysfunction and provides information about the patient's overall breathing ability. The MVV is sometimes performed in conjunction with and following FVC testing.

NOTE!

This test requires considerable effort and motivation on the part of the patient. It is fatiguing and patient effort dependent. It may induce gas trapping or bronchospasm. It is not recommended for routine screening procedures.

The MVV correlates well with a patient's exercise capacity and is used as a predictor of the maximum ventilatory capacity.

To perform the MVV test, do the following:

1. Explain the procedure to the patient so that he or she fully understands what will happen.
2. Highlight the patient's name in the **Browse Patient List** window.
3. Click the **MVV Tests** button.

NOTE!

Insert a new Spiro-Filter into the flow sensor for each new patient.

4. Have the patient breathe in and out as hard and fast as possible for at least 12 seconds.
5. From the **MVV Tests** window, click the **Perform MVV** button.

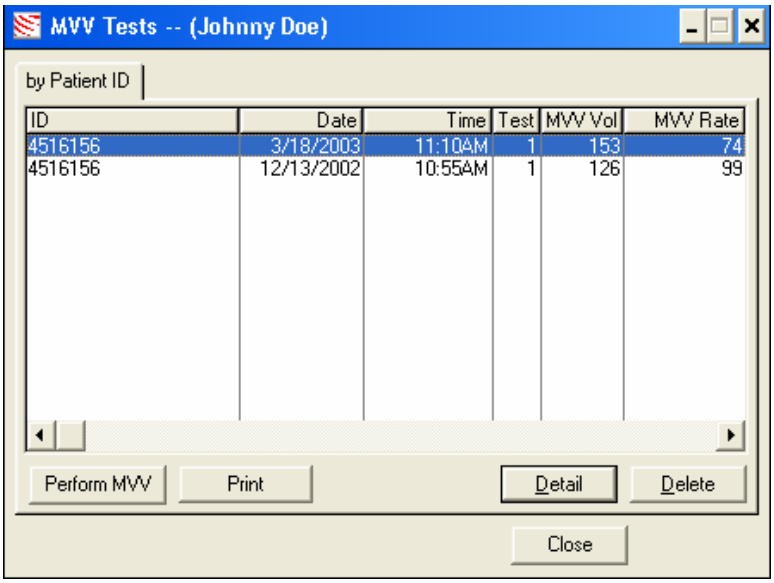


Figure 5-16: *MVV Tests Window.*

6. When the **Hold SENSOR STEADY** window appears click **OK**.

7. Place nose clips on the patient and instruct the patient in the following manner with:

   a. "Place your mouth on the mouthpiece with your tongue under the mouthpiece."

   b. "Breathe in and out as hard and fast as possible. Continue this forced panting until I tell you to stop. It will be about 12 seconds."

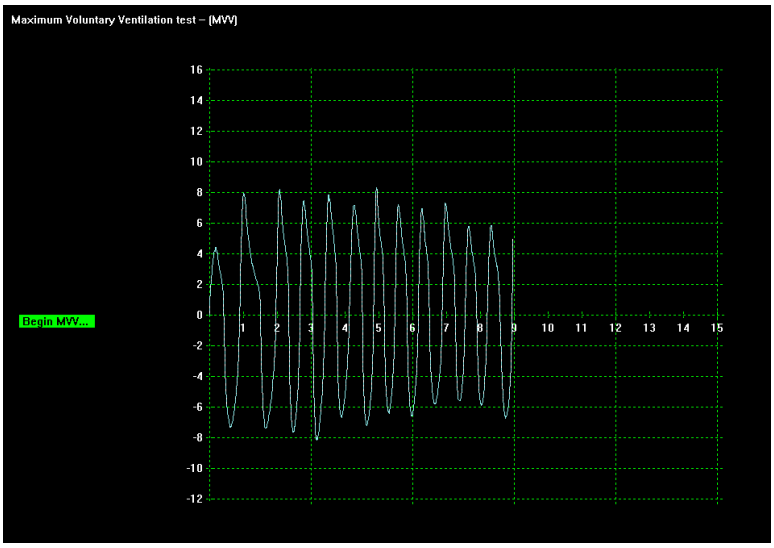


Figure 5-17: *MVV Graph Window.*

The curve moves up and down, displaying the volume breathed in and out as well as the respiratory rate. This display indicates the breathing pattern during the MVV maneuver.

8. After the test is complete, the **Accept or Reject MVV Test** window appears.

   An MVV test is "acceptable" if:
   - The patient put forth maximal effort
   - The test lasted a full 12 seconds or more
   - The patient did not cough or choke
   - The result is approximately 35 times the FEV1

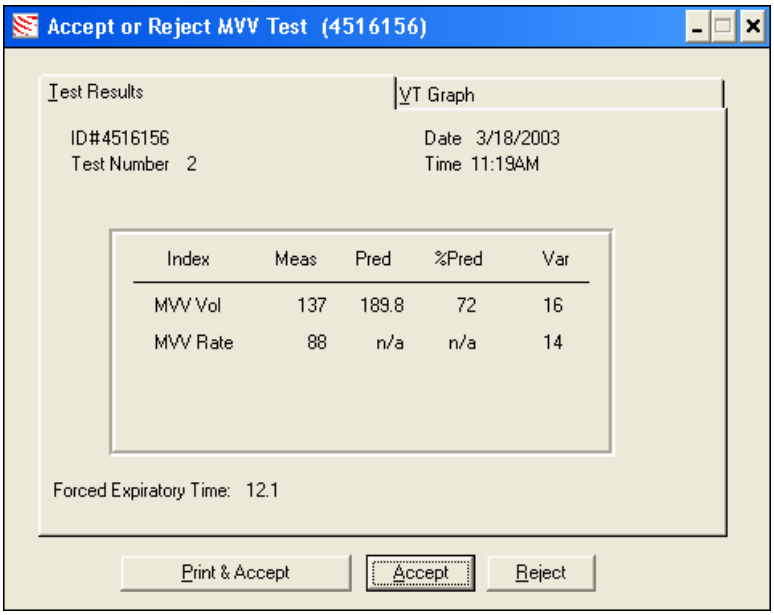


Figure 5-18: *Accept or Reject MVV Test Results Window.*

Options on the **MVV Tests** window shown in Figure 5-16 are:

Perform MVV:
enters MVV testing mode

Print:
prints the numeric test results of the highlighted test when selected later

Detail:
displays the numeric results window

Delete:
deletes the currently highlighted test from the data base. Confirmation is required.

9. Click the **Print & Accept** button to accept and print the test.

NOTE!

If the accepted test is not printed at this time, only the numeric test data, *not* the volume-time graph, will be available for printing later.

10. Both window tabs may be clicked for review before making the **Accept** or **Reject** determination. Once the test is rejected, the information for that test is no longer available.
11. Click the **Detail** button to view the **MVV Test Details** window.

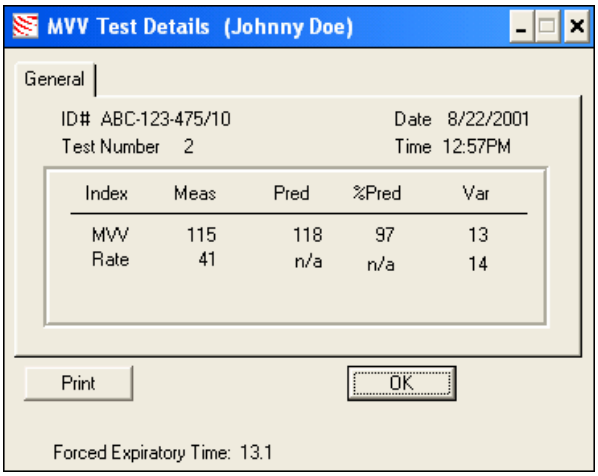


Figure 5-19: *MVV Test Detail Window.*

12. Click the **OK** button to return to the **MVV Tests** window.
13. If you have completed testing this patient, click **Close** to return to the **Browse Patient List** window.

5.5.1 VIEW OR DELETE TEST

To view or delete a test, do the following:

1. Select the patient whose tests you wish to view or delete by highlighting his or her name in the **Browse Patient List** window.
2. Select the type of test to view or delete by clicking the individual test button (**FVC Tests, Pre Test, Meth Chal., VC Tests, MVV Tests**).
3. To view a test, highlight the specific test, then click the **Detail** button.
4. To delete a test, highlight it in the desired test window, then click the **Delete** button.

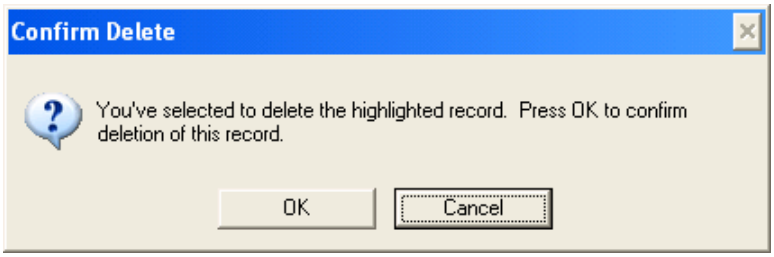


Figure 5-20: *Confirm Delete Window.*

NOTE!

Completing the delete using this procedure will ***permanently*** remove tests from the database.

A **Confirm Delete** window will appear to make sure you truly want to delete the test. Click **OK** to delete or click **Cancel** or the **Esc** key to cancel the operation. These will bring you back to the previous window. Click the **Close** button or the **Esc** key to return to the previous window.

5.6 SUMMARY REPORT

This option allows you to display the summary of the results, along with an interpretation, COPD risk indicator, and lung age estimation.

NOTE!
To learn more about customizing your report summary printing options, see sections 6.1.3 Report Setup and 6.1.4 Report Options.

To prepare a summary report, highlight the name of the patient for whom you want a summary and then click the **Summary Results** button from the **Browse Patient List** window. Options include:

Test Results tab
: Displays the test results for testing that day for the individual selected.

More Test Results tab
: Displays the second page of test results.

FVC Graph tab
: Displays the flow volume loop graph.

VT Graph tab
: Displays the volume time curve.

Print Summary
: Formats and prints a summary report.

Comments
: Allows the clinician to add text comments about this patient. The comments are only viewable from the patient summary window and will not be printed on the final report.

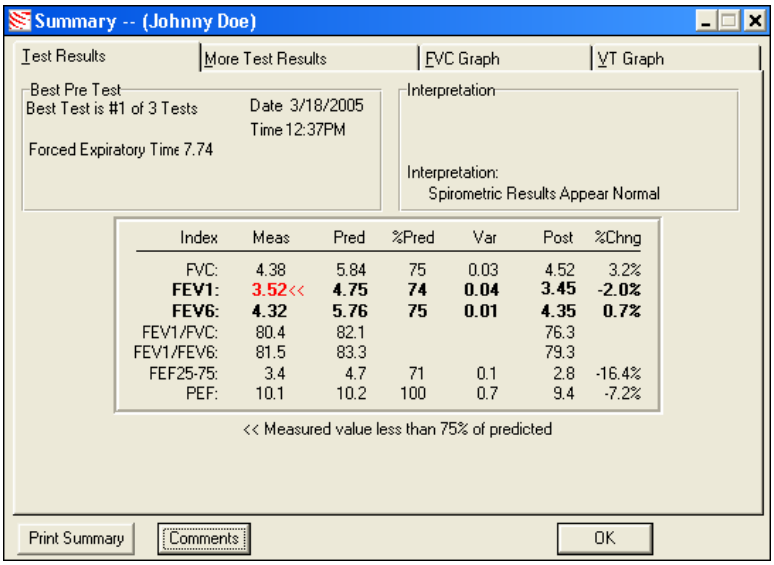

Summary -- (Johnny Doe)
Test Results
More Test Results
FVC Graph
VT Graph
Best Pre Test
Best Test is #1 of 3 Tests
Date 3/18/2005
Time 12:37PM
Forced Expiratory Time 7.74
Interpretation
Interpretation:
Spirometric Results Appear Normal
Index Meas Pred %Pred Var Post %Chng
FVC: 4.38 5.84 75 0.03 4.52 3.2%
FEV1: 3.52<< 4.75 74 0.04 3.45 -2.0%
FEV6: 4.32 5.76 75 0.01 4.35 0.7%
FEV1/FVC: 80.4 82.1 76.3
FEV1/FEV6: 81.5 83.3 79.3
FEF25-75: 3.4 4.7 71 0.1 2.8 -16.4%
PEF: 10.1 10.2 100 0.7 9.4 -7.2%
<< Measured value less than 75% of predicted
Print Summary
Comments
OK

Figure 5-21: *Summary Window.*

The following examples illustrate one-page and two-page printed summary reports.

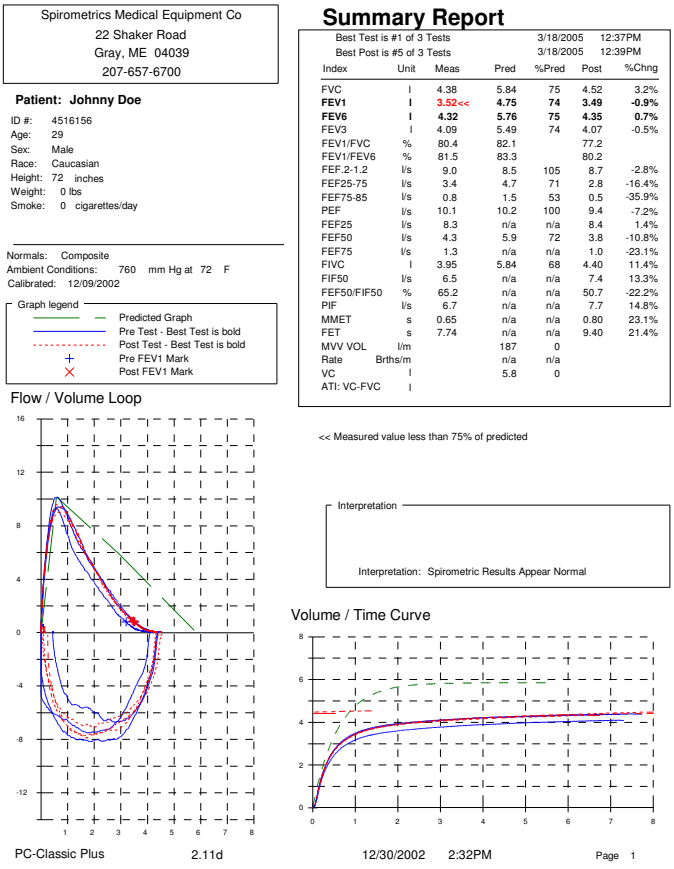
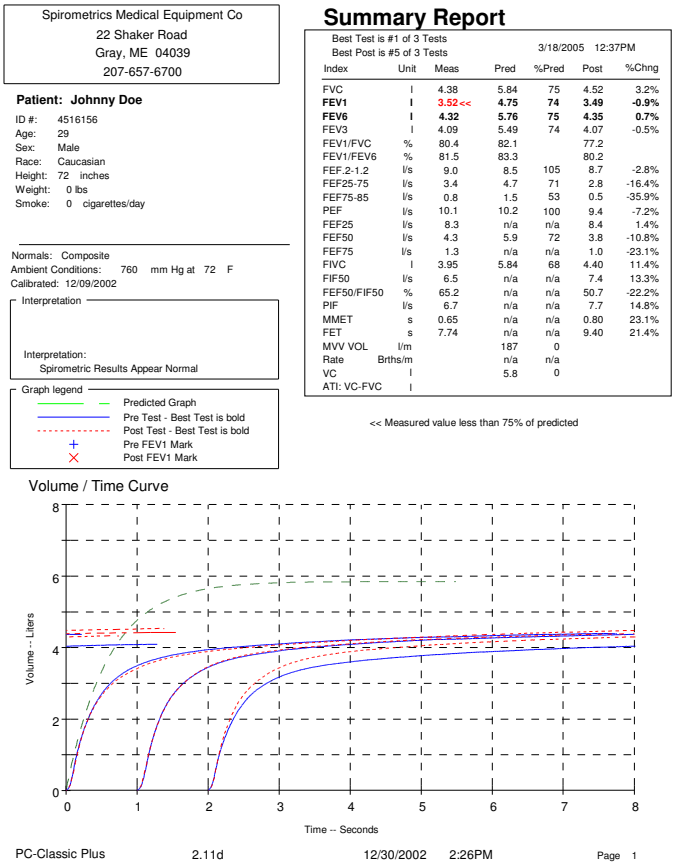

Spirometrics Medical Equipment Co
22 Shaker Road
Gray, ME 04039
207-657-6700
Patient: Johnny Doe
ID #: 4516156
Age: 29
Sex: Male
Race: Caucasian
Height: 72 inches
Weight: 0 lbs
Smoke: 0 cigarettes/day
Normals: Composite
Ambient Conditions: 760 mm Hg at 72 F
Calibrated: 12/09/2002
Graph legend
Predicted Graph
Pre Test - Best Test is bold
Post Test - Best Test is bold
Pre FEV1 Mark
Post FEV1 Mark
Flow / Volume Loop
Summary Report
Best Test is #1 of 3 Tests 3/18/2005 12:37PM
Best Post is #5 of 3 Tests 3/18/2005 12:39PM
Index Unit Meas Pred %Pred Post %Chng
FVC l 4.38 5.84 75 4.52 3.2%
FEV1 l 3.52<< 4.75 74 3.49 -0.9%
FEV6 l 4.32 5.76 75 4.35 0.7%
FEV3 l 4.09 5.49 74 4.07 -0.5%
FEV1/FVC % 80.4 82.1 77.2
FEV1/FEV6 % 81.5 83.3 80.2
FEF.2-1.2 l/s 9.0 8.5 105 8.7 -2.8%
FEF25-75 l/s 3.4 4.7 71 2.8 -16.4%
FEF75-85 l/s 0.8 1.5 53 0.5 -35.9%
PEF l/s 10.1 10.2 100 9.4 -7.2%
FEF25 l/s 8.3 n/a n/a 8.4 1.4%
FEF50 l/s 4.3 5.9 72 3.8 -10.8%
FEF75 l/s 1.3 n/a n/a 1.0 -23.1%
FIVC l 3.95 5.84 68 4.40 11.4%
FIF50 l/s 6.5 n/a n/a 7.4 13.3%
FEF50/FIF50 % 65.2 n/a n/a 50.7 -22.2%
PIF l/s 6.7 n/a n/a 7.7 14.8%
MMET s 0.65 n/a n/a 0.80 23.1%
FET s 7.74 n/a n/a 9.40 21.4%
MVV VOL l/m 187 0
Rate Brths/m n/a n/a
VC l 5.8 0
ATI: VC-FVC l
<< Measured value less than 75% of predicted
Interpretation
Interpretation: Spirometric Results Appear Normal
Volume / Time Curve
PC-Classic Plus 2.11d 12/30/2002 2:32PM Page 1

Figure 5-22: *One-Page Summary Report.*



Spirometrics Medical Equipment Co
22 Shaker Road
Gray, ME 04039
207-657-6700

Patient: Johnny Doe

ID #: 4516156
Age: 29
Sex: Male
Race: Caucasian
Height: 72 inches
Weight: 0 lbs
Smoke: 0 cigarettes/day

Normals: Composite
Ambient Conditions: 760 mm Hg at 72 F
Calibrated: 12/09/2002

Interpretation

Interpretation:
Spirometric Results Appear Normal

Graph legend
Predicted Graph
Pre Test - Best Test is bold
Post Test - Best Test is bold
Pre FEV1 Mark
Post FEV1 Mark

Summary Report

Best Test is #1 of 3 Tests
Best Post is #5 of 3 Tests
3/18/2005 12:37PM

Index	Unit	Meas	Pred	%Pred	Post	%Chng
FVC	l	4.38	5.84	75	4.52	3.2%
FEV1	**l**	**3.52<<**	**4.75**	**74**	**3.49**	**-0.9%**
FEV6	**l**	**4.32**	**5.76**	**75**	**4.35**	**0.7%**
FEV3	l	4.09	5.49	74	4.07	-0.5%
FEV1/FVC	%	80.4	82.1		77.2	
FEV1/FEV6	%	81.5	83.3		80.2	
FEF.2-1.2	l/s	9.0	8.5	105	8.7	-2.8%
FEF25-75	l/s	3.4	4.7	71	2.8	-16.4%
FEF75-85	l/s	0.8	1.5	53	0.5	-35.9%
PEF	l/s	10.1	10.2	100	9.4	-7.2%
FEF25	l/s	8.3	n/a	n/a	8.4	1.4%
FEF50	l/s	4.3	5.9	72	3.8	-10.8%
FEF75	l/s	1.3	n/a	n/a	1.0	-23.1%
FIVC	l	3.95	5.84	68	4.40	11.4%
FIF50	l/s	6.5	n/a	n/a	7.4	13.3%
FEF50/FIF50	%	65.2	n/a	n/a	50.7	-22.2%
PIF	l/s	6.7	n/a	n/a	7.7	14.8%
MMET	s	0.65	n/a	n/a	0.80	23.1%
FET	s	7.74	n/a	n/a	9.40	21.4%
MVV VOL	l/m		187	0		
Rate	Brths/m		n/a	n/a		
VC	l		5.8	0		
ATI: VC-FVC	l					

<< Measured value less than 75% of predicted

Volume / Time Curve

PC-Classic Plus 2.11d 12/30/2002 2:26PM Page 1

Figure 5-23: *Two-Page Summary Report - Page 1.*

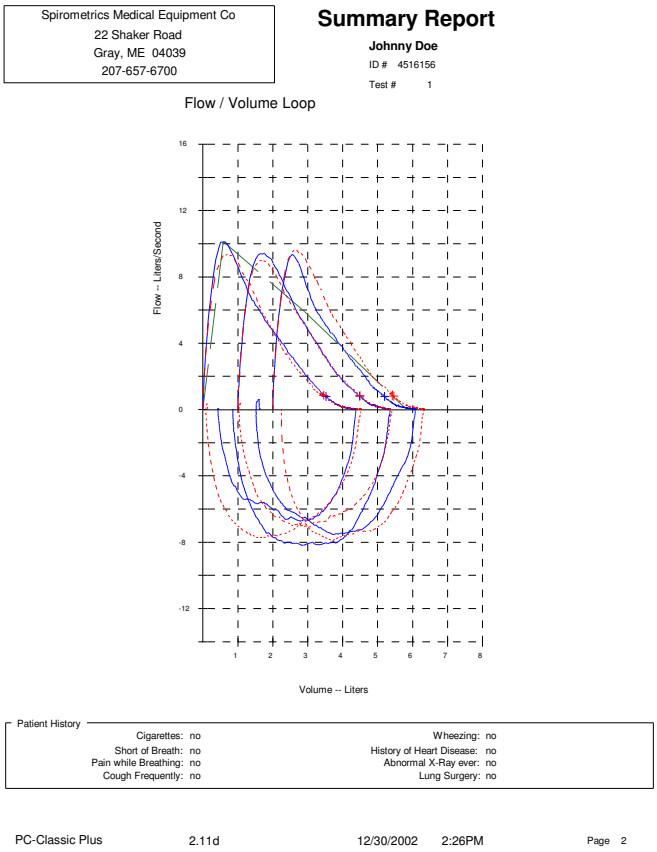


Figure 5-24: *Two-Page Summary Report-Page 2.*

NOTE!

When the necessary predicted normal values are available in the selected normals table, the report graphs will contain a predicted curve. See the section 6.1.1 Software Customization and the Normals Tables section of the Appendix for more information.

5.7 TREND ANALYSIS

The Trend Analysis option, found in both the PC Classic and PC Classic Plus versions, allows you to choose tests and plot the values over time. This allows you to view graphically the change in the patients' lung function over time.

To prepare a trend analysis, do the following:

1. Click the **Trend** button in the Browse Patient List window. Alternatively, click **File** to access the pull down menu. Click **Trend Analysis** to display the Trend Analysis window.

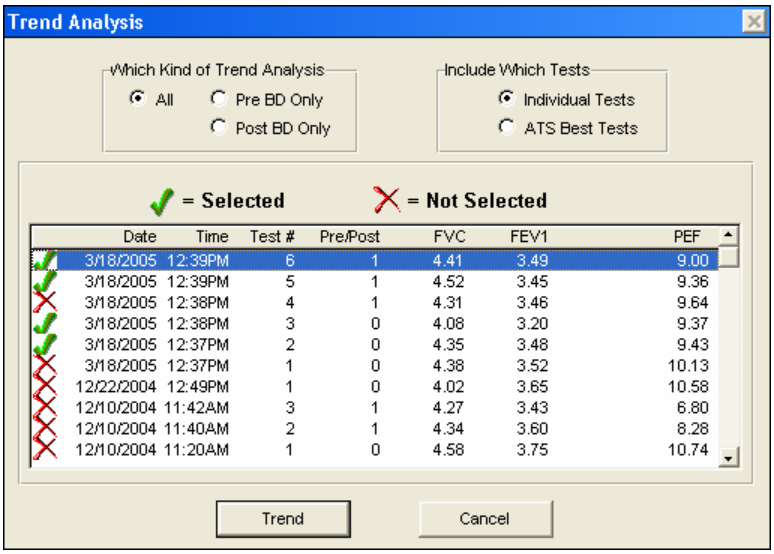


Figure 5-25: *Trend Analysis Window.*

2. You may compare individual tests or the best test results, from **All tests**, **Pre BD Only** or **Post BD Only** (Bronchodilator).

3. Make selections within the **Which Kind of Trend Analysis** and **Include Which Tests** boxes and then highlight the tests from those displayed in the **Select** area.

4. Use the scrollbar, press the arrow keys or press the **PgUp** or **PgDn** keys to move within the available tests.

5. Press the **Space Bar** or **double click** to tag tests for trending. Tests are tagged to be trended when the icon to the left is a ✓. Up to twenty (20) tests maybe selected to trend.

6. If you have selected a test that you wish to de-select, highlight it and press the **Space Bar** or **double click** the test. The test is not tagged for trending when the icon to the left is an ✗.

7. Five indices are trended: FVC, FEV1, FEV1/FVC, FEF 25-75, and PEF. Click the **Trend** button to display the **Trend Analysis** window with its two (2) tabs:

   The **Trend Data** tab displays the numeric results, with each line showing the date the test was performed, the specific test number for that day, the respective indices, and a column indicating Pre or Post bronchodilator testing results. A zero (0) indicates that it was Pre testing; a one (1) shows it as a Post test.

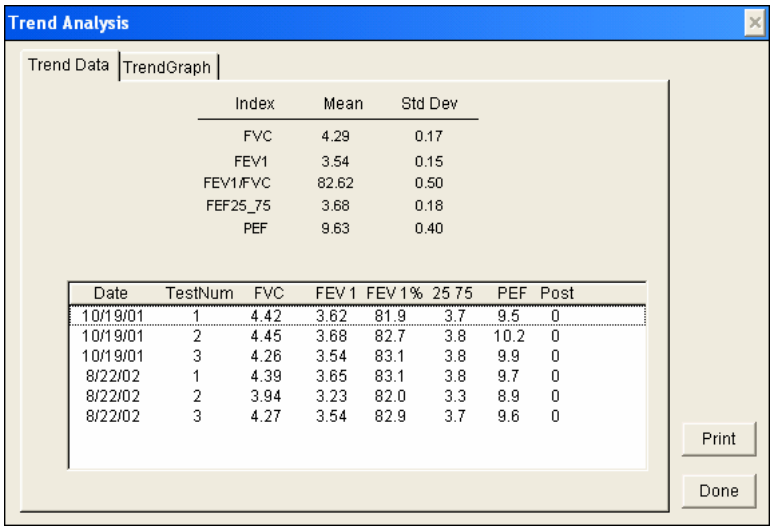


Figure 5-26: *Trend Analysis: Trend Data Tab.*

The **Trend Graph** tab will open a graph window and display a plot of the indices.

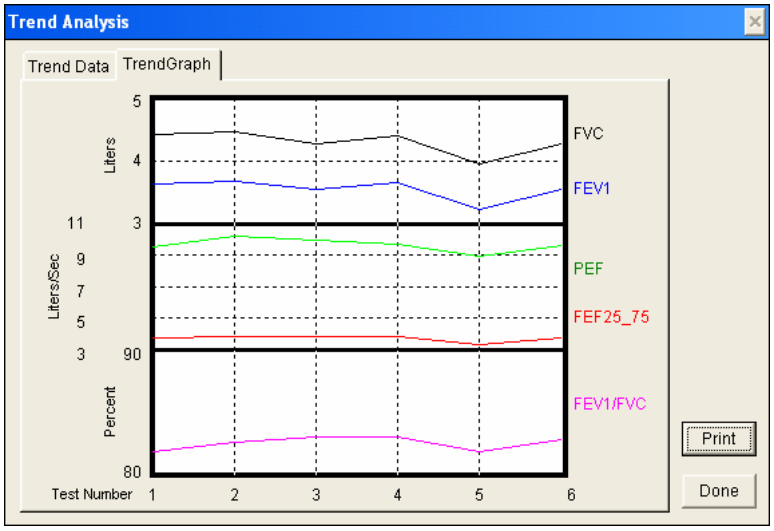


Figure 5-27: *Trend Analysis: Trend Graph Tab.*

To print a copy of the trend analysis, click the **Print** button. To return to the previous window click the **Done** button, or press the **Esc** key. The test number corresponds to date from the oldest to most recent record.

NOTES

Chapter 6: *SPECIAL FEATURES*

6.1 CUSTOMIZATION

Spirometrics designed the PC Classic and PC Classic Plus to be as flexible as possible, allowing users to customize it to meet their particular needs.

To customize your software settings, open the **Customization** window, by clicking on the **Customization** option of the main menu.

6.1.1 SOFTWARE CUSTOMIZATION

The **Setup** tab contains fields that allow you to customize your software. The following variables are included in this window:

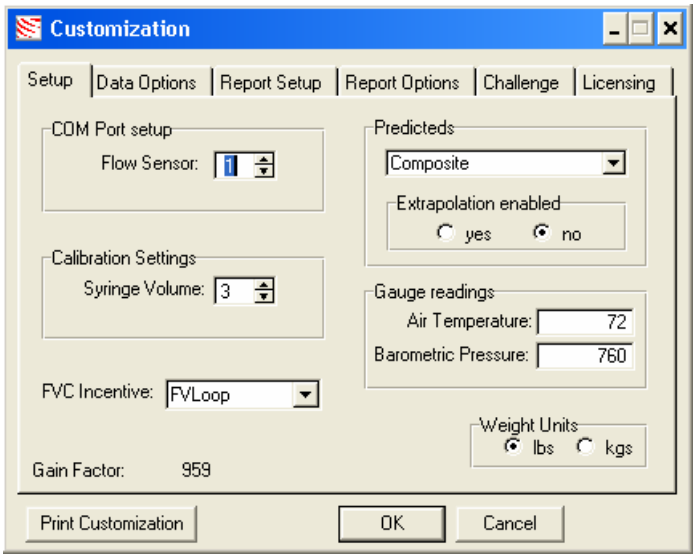


Figure 6-1: *Customization - Setup.*

COM Port setup (Flow Sensor)

To change the COM Port, highlight the number for COM Port Flow sensor and enter the number of the COM port to be used. Alternately, use the scrollbar, or press the up or down arrow keys on the keyboard, to arrive at the number you desire.

Predicteds

The default setting is **Composite**. To change it, access the pull-down menu by clicking the ▼ button. Scroll through the listed studies, highlight the author you want to use and click on it. The choices are: ***Composite***, ***Crapo***, ***ECCS***, ***Hsu***, ***Knudson-1983***, ***Knudson-1976***, ***Lam, Morris, NHANES III, and Polgar***. Refer to the REFERENCES section in the Appendix for selection guidance.

Extrapolation

The default setting is **no**, indicating that the predicted will not be extrapolated. By changing this field to **yes**, the predicted will be reported even though the height or age range was not captured in the author's study. The predicted will be identified as being extrapolated when displayed on-screen and in the report(s).

Calibration Settings (Syringe Volume)

The default setting is **3 liters**. To change it, use the up and down arrows on the keyboard or highlight the existing number and enter the appropriate number.

Gauge readings

Allows you to change the settings for air temperature and barometric pressure each day of testing. To do so, highlight the field and enter the appropriate number. (Temperature values from 10 to 40 are recorded as ° C and those from 50 to 104 as °F. Barometric pressure values from 20 to 35 are recorded as inches Hg, and from 500 to 900 are recorded as mmHg). These values must be accurate for each individual tested.

FVC Incentive Display

The default setting is Flow Volume loop (**FVLoop**). The choices are: **FVLoop** (Flow-Volume Loop), **VTCurve** (Volume-Time Curve), and **Balloons**.

Weight Units

The default setting is **lbs** (pounds). To change it, select **kgs** (kilograms).

Gain Factor

This variable is set during calibration. It is only displayed on the **Setup** window and cannot be changed.

6.1.2 DATA OPTIONS

The **Data Options** tab allows customization of the security, backup and data location settings.

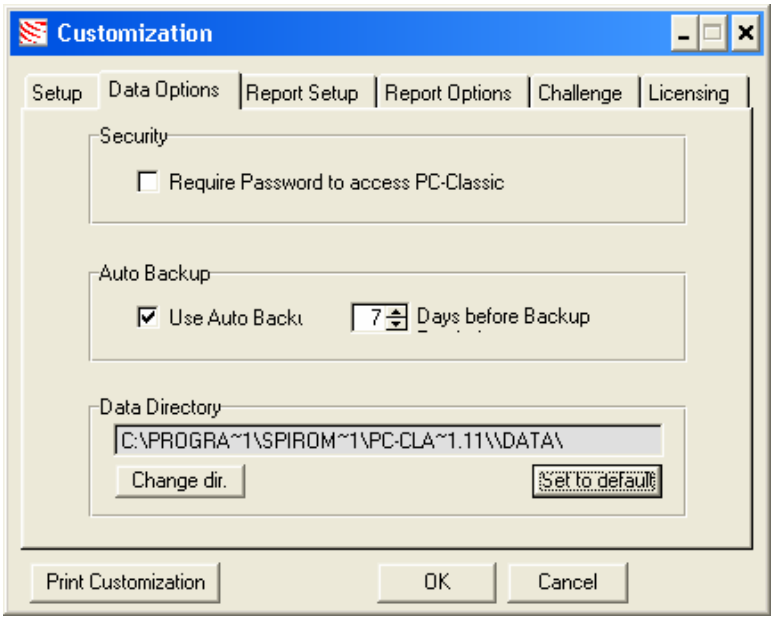


Figure 6-2: *Customization - Data Options.*

Security

The program can be set to require a password for all individuals to access to the PC-Classic software and related patient data in order to ensure patient privacy protection. See section 7.5 Maintaining Users to develop a user list and set passwords prior to selecting **Require Password to access PC-Classic**. Section 7.5 also has default password information.

Auto Backup

The default setting for automatic backup is for all data to be backed up when exiting the program. The interval between each backup may be selected from 1 to 30 days.

Data Directory

The data directory is set to the default location during installation. This setting may be changed by selecting the **Change Dir** button and entering the new data directory location. The **Set to Default** option resets the data path to the data subdirectory of the program directory. Both short and long filenames may be used.

6.1.3 REPORT SETUP

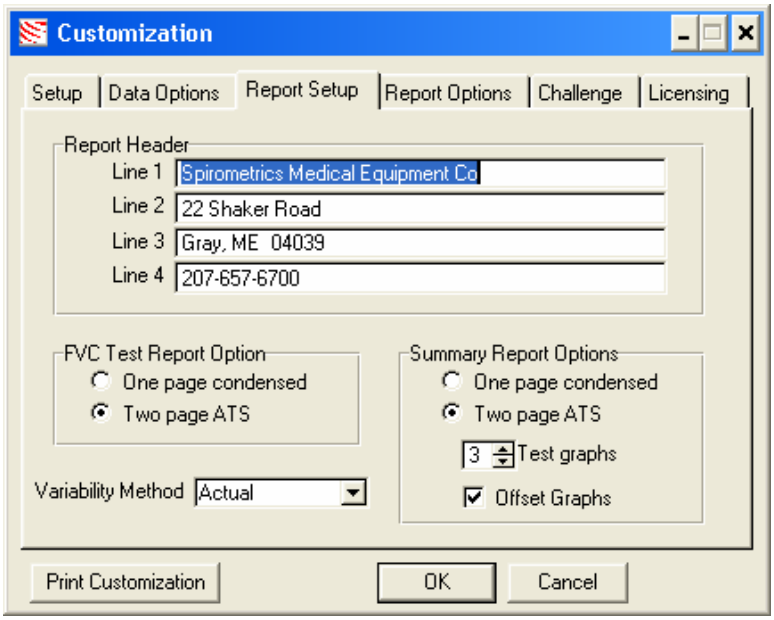


Figure 6-3: *Customization - Report Setup.*

The **Report Setup** tab allows customization of the report printout.

Report Header: Allows four (4) lines of text to identify the facility performing the testing.

FVC Test Report Option

The default setting is **Two page ATS** (graph scaling meets ATS recommendations for hand measurements). The other option is a **One page condensed** report. (Note: condensed graph scaling does not meet ATS recommendations, but is quick and will print both graphs on a single page).

Summary Report Options

The default is set to **Two page ATS** (graph scaling meets ATS recommendations for hand measurements). As in the FVC Test Report Options, a single **One page condensed report** is also available. Up to **3 graphs** may be included in the pre- and post-bronchodilator report. The graphs may be placed directly on top of each other or slightly offset.

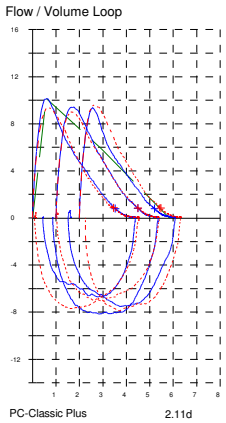


Figure 6-4: *Offset Graphs Example.*

When **Offset Graphs** is selected, the graphs will be offset 0.5 liters at Residual Volume (RV) in the summary report.

NOTE!

Spirometrics recommends that at least 3 acceptable graphs should be available for review by the interpreting physician.

Variability Method

The default variability method is set to **Actual**, which will display the absolute differences and will note the FVC or FEV1 differences from the best to the second best test above 0.20 liters. (ATS 1994 method) Optionally, the variability method may be set to **Percent**, which will display percentage differences and will note FVC or FEV1 percent differences from the best to the second best test that are greater than five (5%) percent. (ATS 1987 method)

6.1.4 REPORT OPTIONS

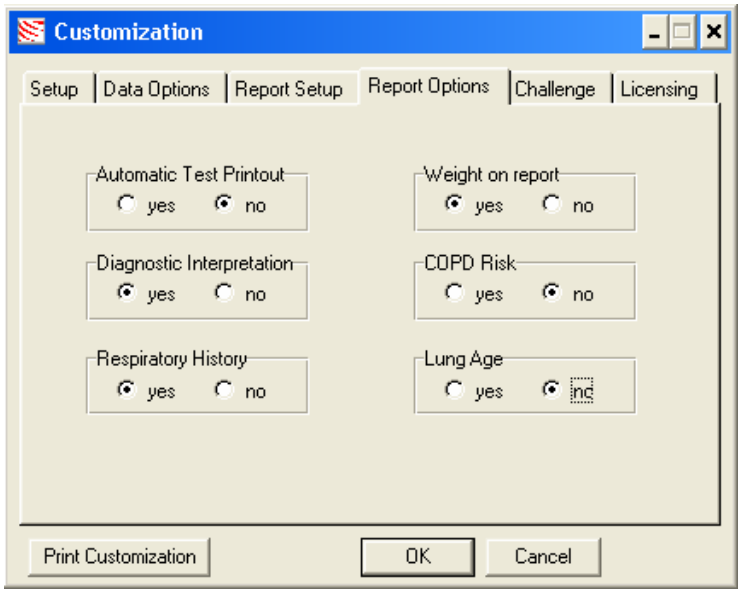


Figure 6-5: *Customization - Report Options.*

The **Report Options** window allows you to customize whether listed indices or a list of information will appear on the individual and summary reports.

The window comprises the following fields:

Automatic Test Printout
The default setting is **no**.

Weight on report
The default setting is **yes**.

Diagnostic Interpretation
The default setting is **no**. See the Diagnostic Interpretation section of the Appendix for more information.

COPD Risk
The default setting is **no**.

Respiratory History
The default setting is **yes**.

Lung Age
The default setting is **no**.

6.1.5 METHACHOLINE CHALLENGE OPTIONS

WARNING: Methacholine is an inhaled agent that may cause the airways to constrict in susceptible patients. The 1999 ATS guidelines for methacholine and exercise testing should be followed. (See the REFERENCES section in the Appendix.)

Users can customize the methacholine challenge settings at the **Challenge** tab.

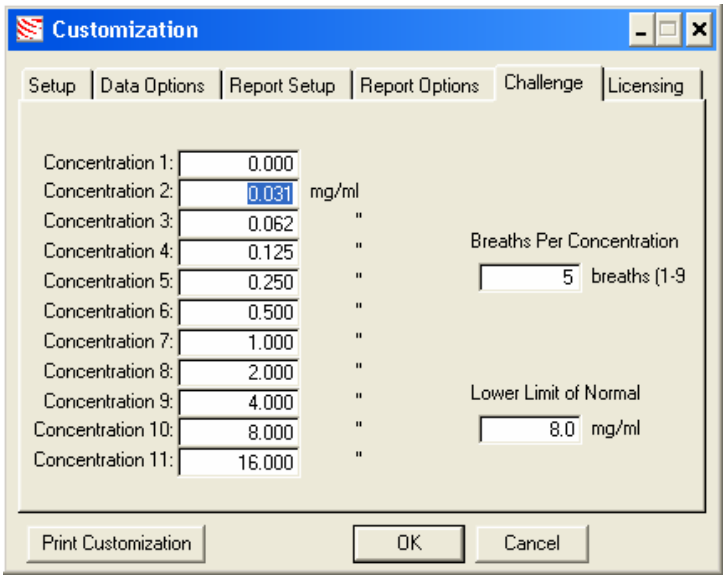


Figure 6-6: *Customization - Methacholine Options.*

Breaths Per Concentration

The default setting is **5** breaths. Selection range is one (1) to nine (9). To change the number, click on the number or press the **Tab** key repeatedly to reach the field, delete the old value, and enter the new one.

Concentration

Concentration 1 is always a baseline diluent. The defaults for levels two (2) through eleven (11) are 0.031, 0.062, 0.125, 0.25, 0.50, 1, 2, 4, 8, 16 mg/ml/breath, respectively. These are consistent with the 1999 ATS recommendations for dosing protocols. To change any of the present values, click on the number or press the **Tab** key repeatedly to reach the appropriate field, delete the old value, and enter the new value.

Lower Limit of Normal

This is used in the interpretation statement. The default setting is 8.0 mg/ml. To change the number, click on the number or press the **Tab** key repeatedly to reach the appropriate field, delete the old value, and enter the new value.

6.1.6 LICENSING

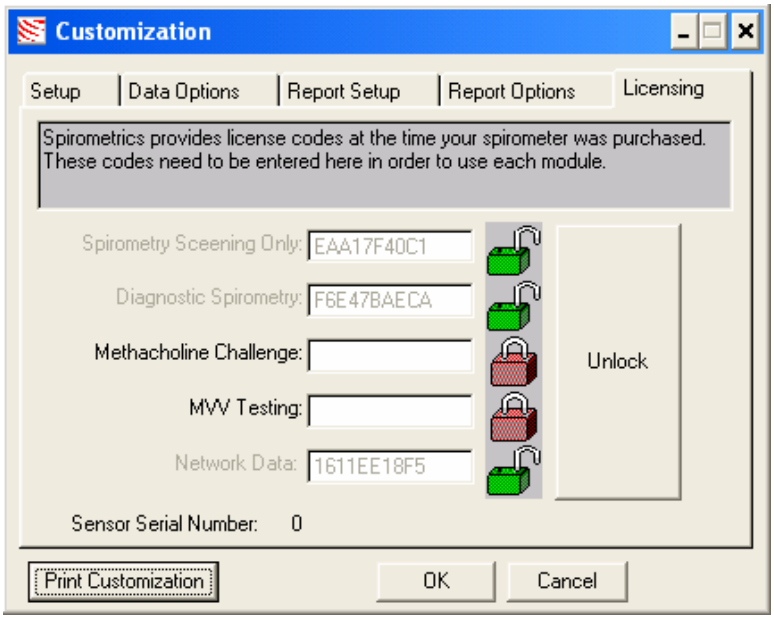


Figure 6-7: Customization - *Licensing*.

The **Licensing** tab allows entry of a license code for each module purchased. Spirometrics has provided each of these codes with the equipment at the time of purchase or upgrade. For a list of license codes provided when your system was originally purchased, see the first page of this manual or the PC Classic CD packaging.

Enter each code and click **Unlock**. Notice the padlock symbol turns green when a module is activated.

6.1.7 General Customization Buttons

The following buttons are located at the bottom of the **Customization** window:

- The **Print Customization** button allows you to print a copy of the customization settings that you have just made, in case you share the equipment with others who might change the settings. The default system printer will be used.

NOTE!
We recommend that you make a copy of your customization settings and keep it with the user's manual.

- The **OK** button allows you to accept all changes that you have made.
- The **Cancel** button allows you to cancel the changes that you have made and abort the customization session.

6.2 Performance Verification & Calibration

We have included a routine called **Performance Verification** for PC Classic users and a **Calibration** routine for PC Classic Plus users to test the long-term stability of the system. Performance verification or calibration was completed as part of the installation process. These procedures can be repeated at any time to validate that the spirometer is working properly. ATS standards require daily calibration. For more information on the calibration option and ATS requirements see section 6.3 Calibration (PC *Classic Plus Only)*.

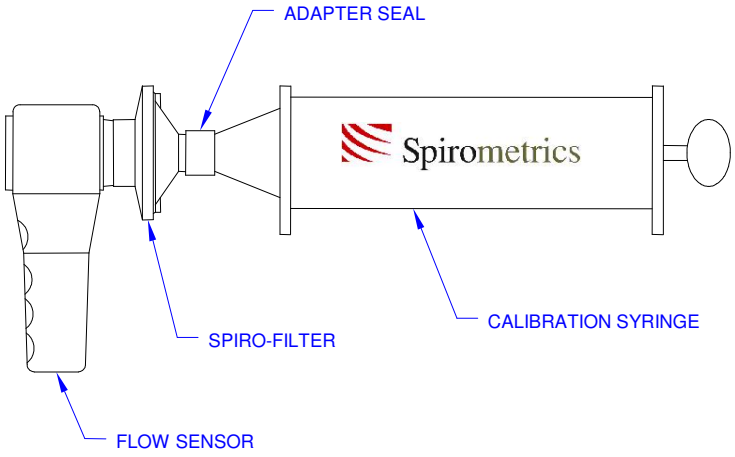


Figure 6-8: *Flow Sensor and 3-Liter Syringe.*

To connect the 3-liter syringe to the flow sensor, do the following:

1. Connect the adapter seal to the end of the 3-liter syringe.
2. Connect the flow sensor mouthpiece firmly to the 3-liter syringe.

Once the syringe is firmly connected, follow the routine for the software you have purchased, described in the following sections.

6.2.1 PERFORMANCE VERIFICATION ROUTINE (*PC CLASSIC ONLY*)

If you purchased the PC Classic, the **Performance Verification** window can be accessed after installation and initial setup of the software at any time by clicking on the **Performance Verification** button.

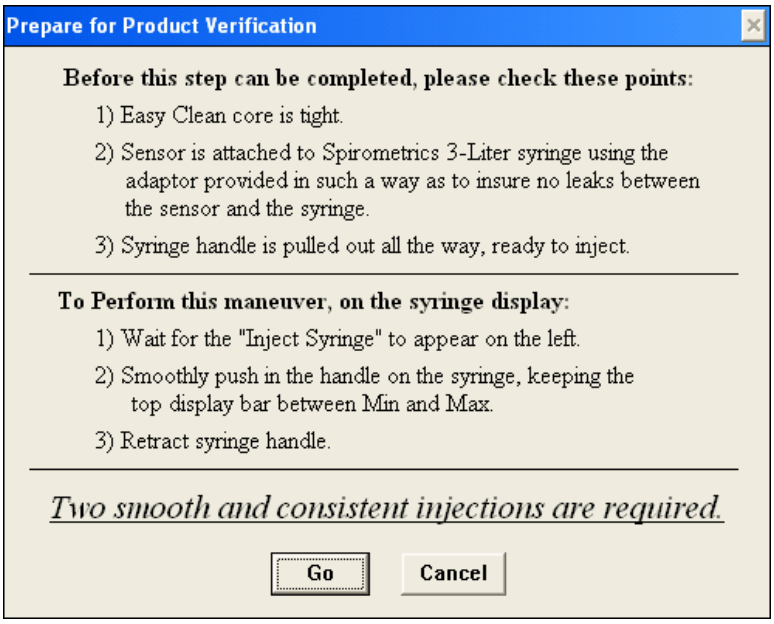

Prepare for Product Verification
Before this step can be completed, please check these points:
1) Easy Clean core is tight.
2) Sensor is attached to Spirometrics 3-Liter syringe using the adaptor provided in such a way as to insure no leaks between the sensor and the syringe.
3) Syringe handle is pulled out all the way, ready to inject.
To Perform this maneuver, on the syringe display:
1) Wait for the "Inject Syringe" to appear on the left.
2) Smoothly push in the handle on the syringe, keeping the top display bar between Min and Max.
3) Retract syringe handle.
Two smooth and consistent injections are required.
Go
Cancel

Figure 6-9: *Prepare for Product Verification Window.*

The following steps describe how to complete the performance verification sequence:

1. Click the **Perform Verification** button. The Prepare for Product Verification window will appear.
2. Read the instructions carefully.
3. Click **Go** when ready to proceed. A full-screen display that shows the syringe injection will appear.

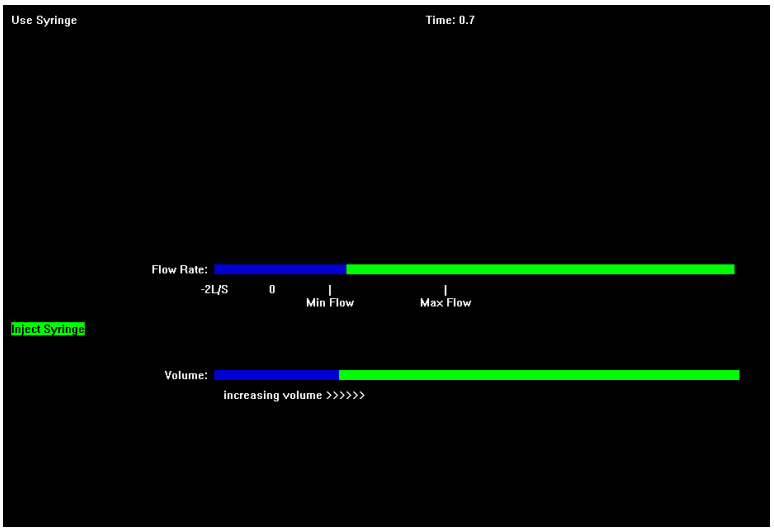


Figure 6-10: *Full-screen Display – Syringe Injection.*

4. Wait for the "**Inject Syringe**" command to appear on the left.
5. Pull the handle to its farthest extent.
6. Push in the handle. Be sure to use a steady, continuous stroke in such a manner that the scroll bar remains between the "**Min Flow**" and "**Max Flow**" markers.
7. When done, immediately pull the handle back all the way. The full-screen display will reappear.
8. Repeat steps 4 through 6, following the on-screen prompts, until a window appears, reporting the measured results.

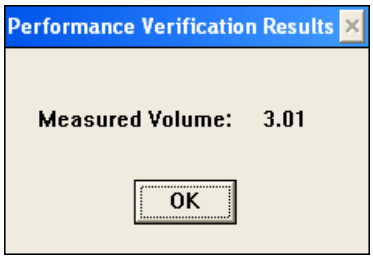


Figure 6-11: *Performance Verification Results.*

9. Click **OK** to complete the verification procedure.

6.3 CALIBRATION (*PC CLASSIC PLUS ONLY*)

Calibrating your PC Classic Plus ensures accurate test results. You should calibrate before you use it for the first time, and recalibrate it at routine intervals. Spirometrics recommends daily calibrations to insure that the spirometer is working properly.

NOTE!

For compliance with the American Thoracic Society's 1994 *Standards of Spirometry* and good quality control procedures, it is recommended that the linearity of the flow sensing pneumotach be checked on a daily basis. This can be accomplished by injecting your syringe at three different flow rates during a follow-up injection. As an example, injecting a 3-liter syringe for 1, 3, and 6 seconds will create rates of 3 l/s, 1 l/s, and 0.5 l/s, respectively. See the following section for instructions.

6.3.1 CALIBRATION ROUTINE

The following steps describe how to complete the calibration sequence:

1. Click the **Calibration** button. The **Calibration** dialog box will appear. It displays the syringe volume.

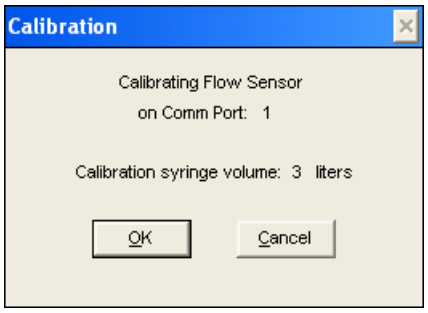


Figure 6-12: *Calibration Dialog Box.*

2. Click **OK** to proceed or **Cancel** to abort the calibration procedure.

NOTE!

To change the syringe volume, the user must access the **Customization** option from the main menu and change the syringe volume. Syringe volumes from 1 to 9 liters may be entered. Using a syringe with volume different from the display value will result in calibration errors.

3. If you selected **OK**, a second dialog box will appear with an instruction to "**Hold SENSOR STEADY**".

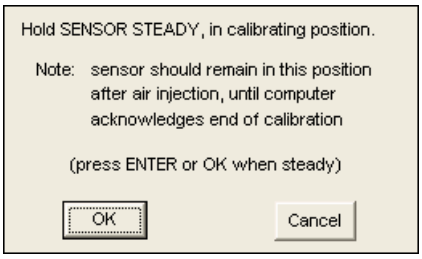

Hold SENSOR STEADY, in calibrating position.
Note: sensor should remain in this position after air injection, until computer acknowledges end of calibration
(press ENTER or OK when steady)
OK
Cancel

Figure 6-13: *Hold Sensor Steady Dialog Box.*

4. Pull the handle to its farthest extent.
5. When ready, click **OK** to proceed. A full-screen display will appear.

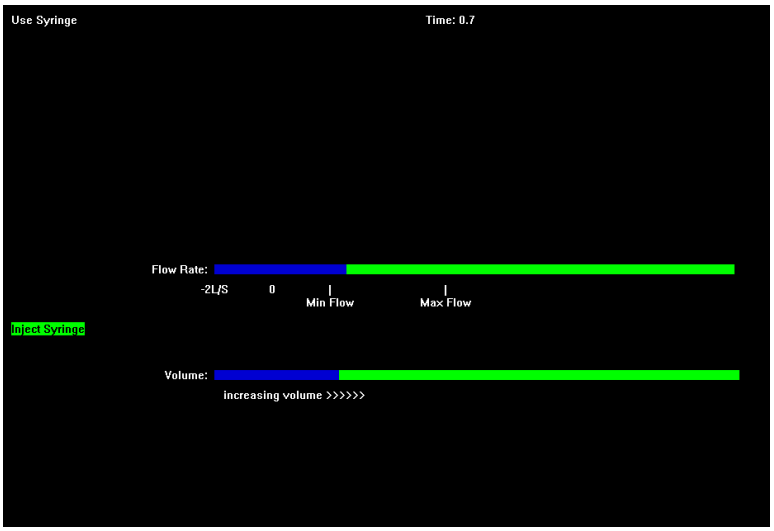


Figure 6-14: *Full-screen Display – Syringe Injection.*

6. Wait for the "**Inject Syringe**" command to appear on the left.
7. Push in the handle. Be sure to use a steady, continuous stroke in such a manner that the scroll bar remains between the "**Min Flow**" and "**Max Flow**" markers.
8. Upon successful completion, a **Verify Calibration** dialog box will appear.
9. Pull the handle back to its farthest extent. Click **OK** to proceed.

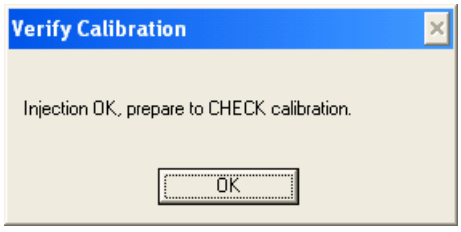


Figure 6-15: *Verify Calibration Dialog Box.*

10. Repeat steps 6 and 7.

11. Upon successful completion, a **Flow Calibration Results** window will appear, denoting that the calibration results are either "**in agreement**" or "**NOT in agreement**". At this point, the user can print a copy of the calibration results or proceed to other calibration options. Calibration records should be maintained for each day testing is performed.

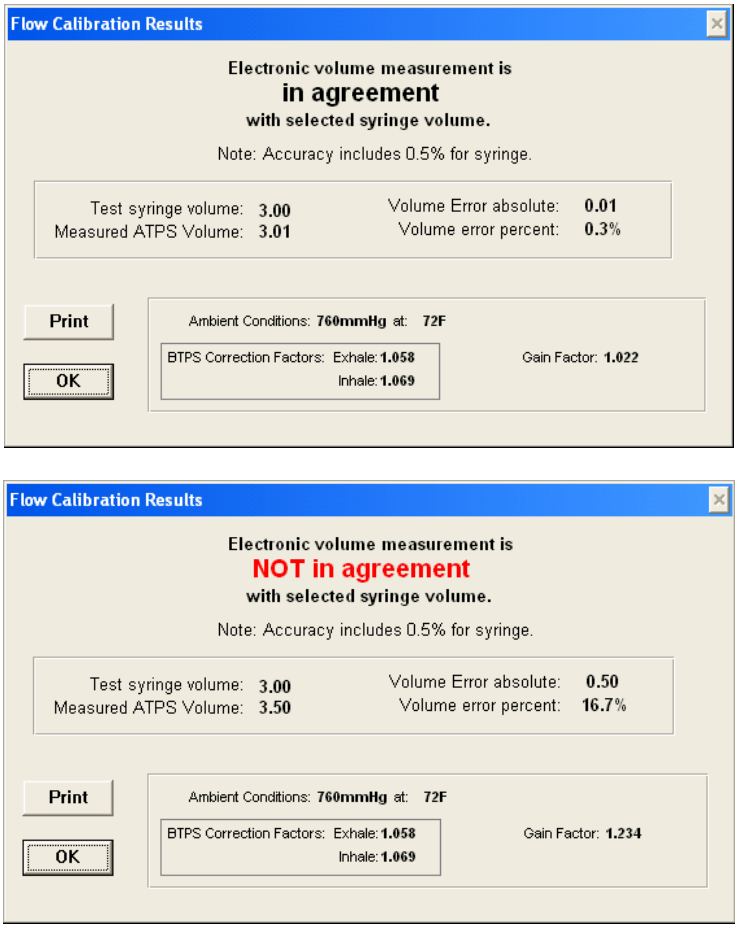


Figure 6-16: *Flow Calibration Results.*

12. When ready to continue, click **OK**. A final calibration dialog box appears, offering three options:
    - Click **Done** to proceed to patient testing.
    - Click **ReStart** to repeat the calibration routine.
    - Click **ReCheck** to verify the calibration over a wide range of flow rates.

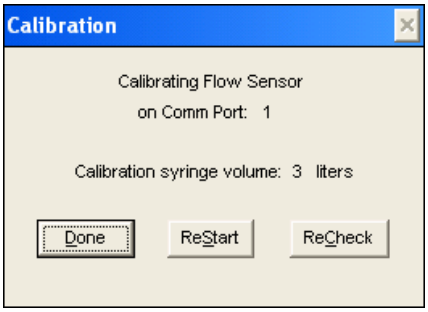


Figure 6-17: *Calibrating Flow Sensor Dialog Box.*

NOTE!

It is important to select the **ReCheck** option to verify the calibration over a wide range of flow rates. This option meets the ATS recommendations for calibration verification over a wide flow range. Proceed with this step as previously during the calibration routine. Each of three syringe injections must be completed separately by selecting **ReCheck**.

- Inject the syringe at a slow rate. (< 2 L/second)
- Inject the syringe at a medium rate. (4 to 6 L/second)
- Inject the syringe at a fast rate. (> 8 L/second)

The calibration window will appear after each injection. It should display "**in Agreement**" at all three flows.

6.4 PRINTER SELECTION

The PC Classic/PC Classic Plus for Windows program uses the default printer selected under Print Manager or Control Panel. If your default printer does not supply satisfactory results, change your printer selection by doing the following: PC Classic/*PC Classic Plus only* determines the Windows system default printer at program start-up. If you use Windows to change the system default printer, you will need to close and restart PC Classic to update the printer selection.

1. From the main menu, select the **File** option.
2. Click on **Print Setup**.
3. Select the **Specific Printer** option.

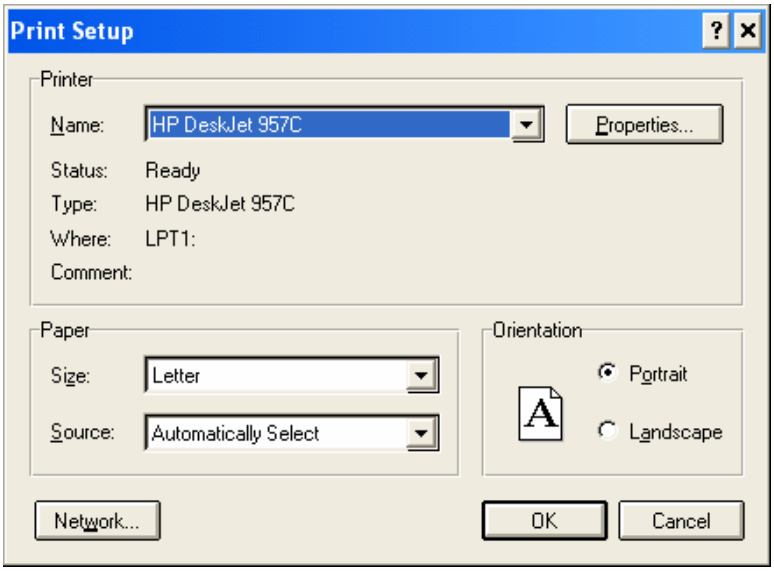


Figure 6-18: *Print Setup* Window.

4. Click the ▼ button to scroll through the printer choices.
5. Highlight the printer that you want to use.

6. Click **OK** to save the selection to disk.

NOTE!
If the print driver supplied by the printer manufacturer gave results that were unacceptable, try installing a different driver from that family, then retry printing. For example, the BJ-130 driver prints the lines darker on the graphs than does the native BJC-210 driver to the BJC-210 printer.

NOTES

Chapter 7: *DATA MANAGEMENT*

7.1 PROTECTING PATIENT DATA

It is recommended that the files located in the DATA directory be regularly backed up.

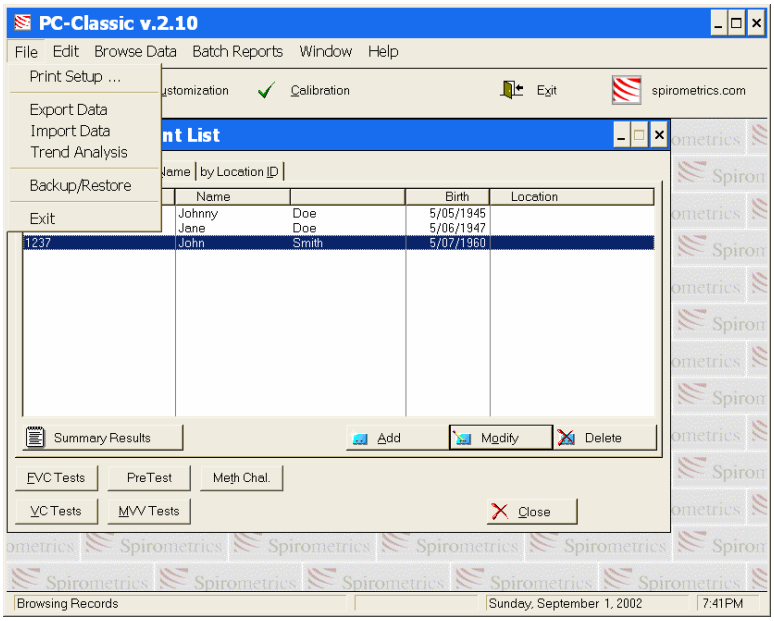


Figure 7-1: *File Options Window.*

To generate a **Backup/Restore** from the main menu:

1. Select **File.**
2. Highlight **Backup/Restore**.

3. A dialog box will appear informing you that the PC Classic program needs to close in order to perform backup and restore procedures. Press the **Enter** key to proceed and PC Classic will close automatically. The **PC Classic - Back Up & Restore** program will open.

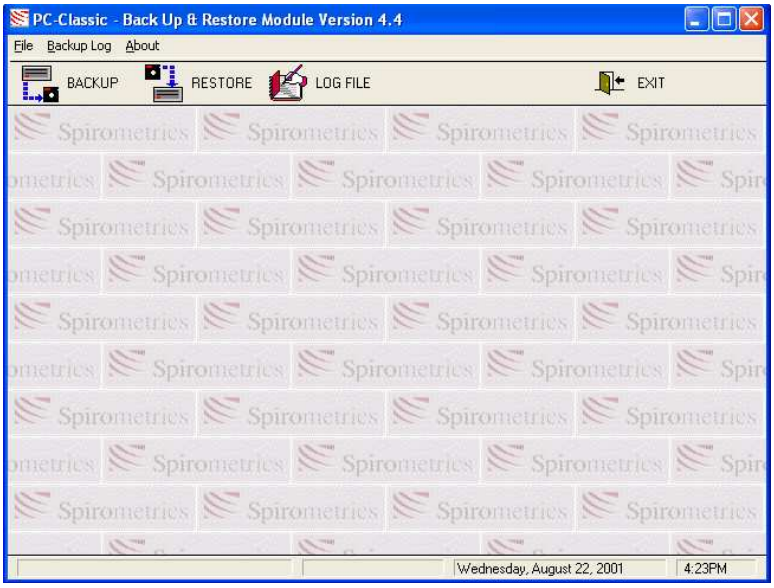


Figure 7-2: *Backup & Restore Console.*

You may **BACKUP** files, **RESTORE** files, or review the backup **LOG FILE** from this screen. Choose the appropriate options and follow the on-screen instructions in each sub-window to perform the desired operation.

4. Click **BACKUP** to back up patient data to floppy or to a directory of your choice.
5. Click **RESTORE** to retrieve patient data from the backup files.
6. Click **LOG FILE** to review all backup and restore history.

Upon exiting the PC Classic program, the following message will appear to allow automatic backup of files:

Backup?
59 days have elapsed since you last backed up your data files.
Current Interval is 4 days.
Would you like to create a new backup now?
Yes
No

Figure 7-3: *Automatic Backup Window.*

Click **Yes** to backup files. PC Classic will close and the **PC Classic - Back Up & Restore** program will open.

7.2 EXPORTING AND IMPORTING FILES

The following sections describe how to export and import files.

7.2.1 EXPORTING FILES

The PC Classic can export patient records to a file. To do so:

1. From the main menu, select **File**.
2. Select **Export Data**.
3. Select **Export File Format** and specific fields to export. The default is checked to **Export All Fields**. If the box is unchecked, specific fields may be selected to export. Fields selected are tagged with a **green** circle.
4. Enter the dates, which start and end the period from which you wish to export data. (The default starts from 1/01/80, and ends with the current date, as read from the computer's current settings.)

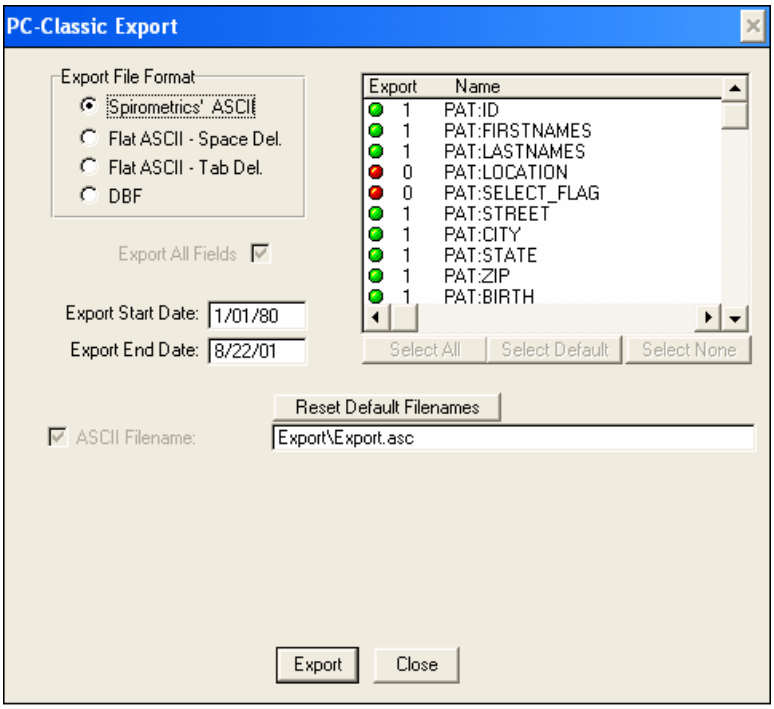


Figure 7-4: *Export Data from PC Classic.*

5. To proceed with exporting, click **Export**. The file will be created and written to your computer's hard drive. To abort exporting, click **Close**.

7.2.2 IMPORTING FILES

The PC Classic can also import patient records to a file. To do so:

1. From the main menu, select **File**.
2. Select **Import Data**.
3. Select **Import File Format**.

4. To proceed with importing, click **Import**. To abort importing, click **Close**.

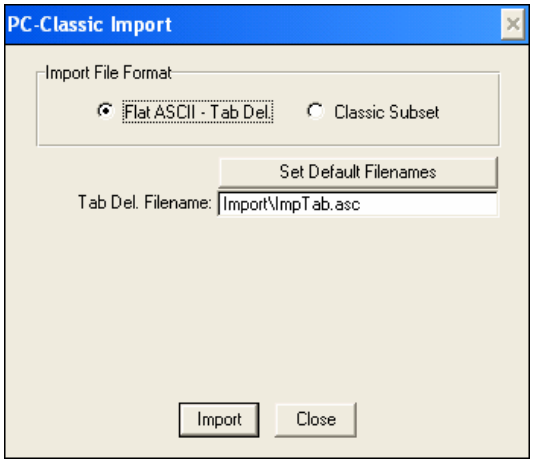


Figure 7-5: *Import Data from PC Classic.*

7.3 BATCH REPORTS

To generate batch reports from the main menu:

1. Select **Batch Reports**.
2. Click on the option that best suits your needs – **Print Patients by ID**, **Print Patients by Name**, **Print Patients by Location ID**, or **Print the Customization**.

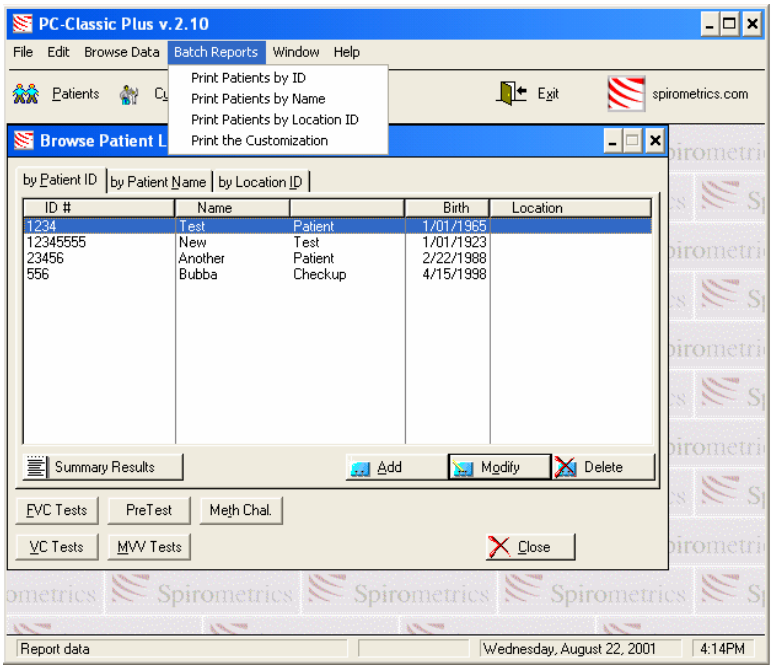


Figure 7-6: *Batch Reports Menu.*

7.4 CALIBRATION REVIEW AND MAINTENANCE

1. Select **Browse Data**.
2. Click on **All Calibrations**. The **Saved Calibrations** window will appear.

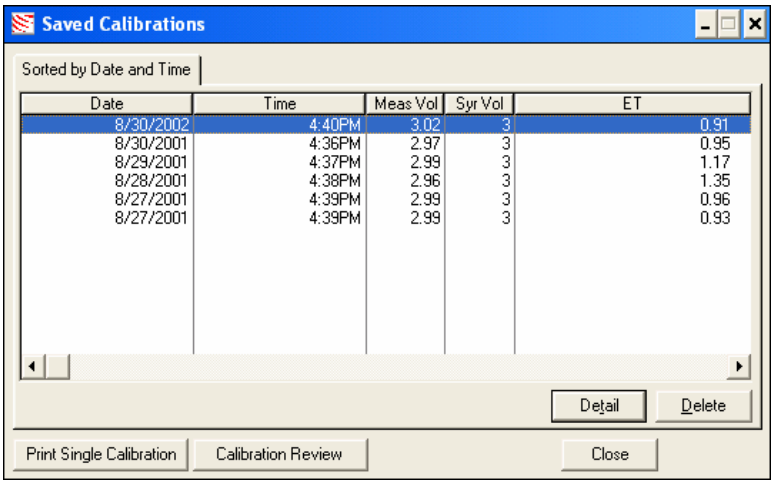


Figure 7-7: *Calibration Data Detail Review Window.*

Date and time are used to sort all calibration data. The data may be reviewed for trending and for evaluation of concerning results. The details of a single calibration can also be examined and printed from this window. The last date of calibration also prints on each patient report.

7.5 MAINTAINING USERS

A list of all system users as entered by a program administrator is maintained by the PC Classic/PC Classic Plus program. A valid username and password is required to run PC Classic/PC Classic Plus software when the security option is selected in the **Data Options** tab of the **Customization** window. See section 6.1.1 Software Customization.

NOTE!

The user list contains the user name MASTER by default. The default password for the MASTER user is master. The username and password are **NOT** uppercase or lowercase character sensitive. The MASTER password may be changed or the MASTER user may be deleted entirely if desired.

WARNING: Store password information in a safe, secure place. The procedure required to recover lost passwords may result in data loss.

The steps necessary to add, delete or modify user information are as follows:

1. Select the **Browse Data** option in the main menu.
2. Click on **Maintain Users** and the **User List** window will appear.

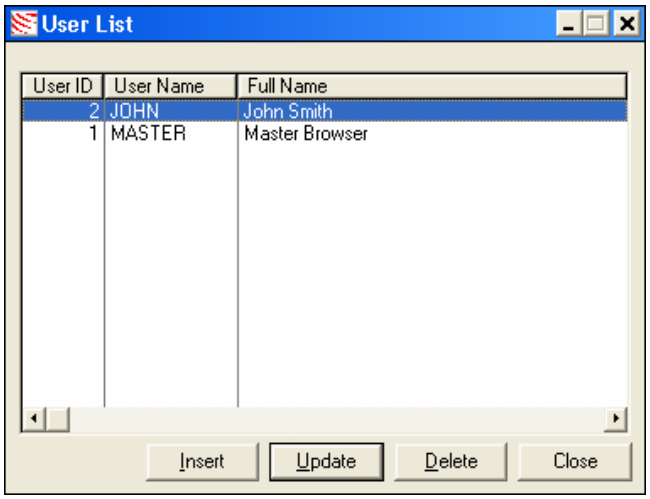


Figure 7-8: *Maintain Users - User List Window.*

3. Click **Insert** to add a new user and password or click **Update** to change a user record. The **Adding a User's Record** or **Changing a User's Record** window will appear.

Figure 7-9: *Adding User Record Window.*

4. Enter or modify the user's information.
5. Click the **Reset** button to add or modify a password for the user.
6. Click **OK** to continue and save the user entry or changes or **Cancel** to abort. The current window will close and return to the **User List** window.
7. If desired, click on **Delete** to permanently remove a user from the PC Classic user list.

7.6 NETWORK OPTION (*PC CLASSIC PLUS ONLY*)

The network option is only available on the PC Classic Plus. The network code may be verified in the **Customization** window in the **Licensing** tab.

Verify that the data directory path is set to your shared location as desired.

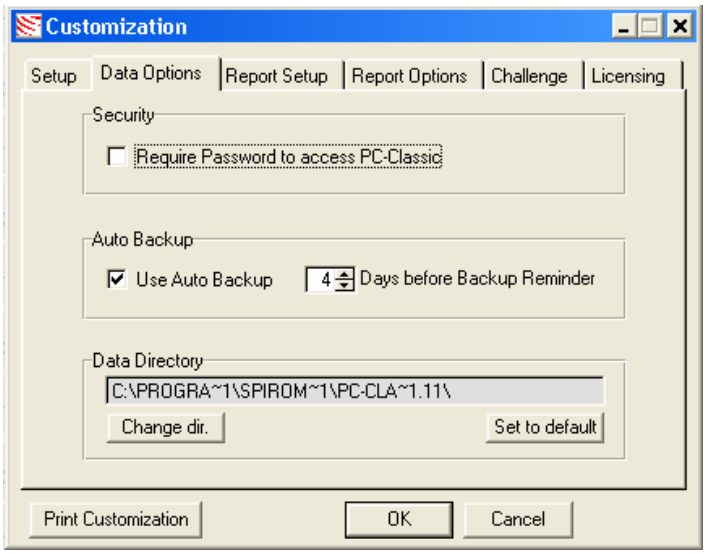


Figure 7-10: *Data Directory Path Setting.*

NOTES

Chapter 8: *CARE AND MAINTENANCE*

8.1 MAINTENANCE OF THE PC CLASSIC FLOW SENSOR

You must disassemble the flow sensor to clean it. Refer to Figure 8-1: Flow Sensor Disassembly. below to learn the names of the different parts of the flow sensor.

CAUTION: Do not use alcohol or attempt to autoclave any part of the PC Classic.

WARNING: To reduce the risk of cross contamination, you must replace the Spiro-Filter after each patient. It is also recommended that the sensor be cleaned after any testing. Federal and state regulations for infection control must be followed.

WARNING: Always unplug the PC Classic before cleaning to avoid electric shock.

8.1.1 REMOVING THE EASY CLEAN CORE

To disassemble the Easy Clean Core, do the following:

1. Unscrew the core by turning it counterclockwise.
2. Continue to turn the core until the threads are disengaged from the handle assembly.
3. Pull out the entire Easy Clean Core when it is no longer engaged with the sensor housing.

CAUTION: DO NOT disassemble the Easy Clean Core. After removal from the sensor handle, it may be cleaned without further disassembly.

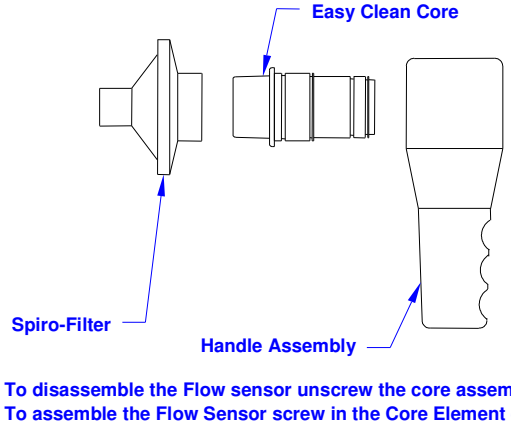

Easy Clean Core
Spiro-Filter
Handle Assembly
To disassemble the Flow sensor unscrew the core assembly counterclockwise
To assemble the Flow Sensor screw in the Core Element clockwise

Figure 8-1: *Flow Sensor Disassembly*.

8.1.2 Cleaning the Easy Clean Core

To clean the flow sensor's core element, do the following:

1. Place the core element in cold sterilization fluid (a protein dissolving solution). Follow the sterilization fluid manufacturer's instructions for disinfecting and sterilizing the core.
2. Be sure to rinse in water thoroughly and allow the core to dry completely before attempting to re-insert the Easy Clean Core into the handle assembly.

8.1.3 Installing the Easy Clean Core

To install the Easy Clean Core, insert the Easy Clean Core into the sensor assembly and tighten by turning until green marker aligns with the pin.

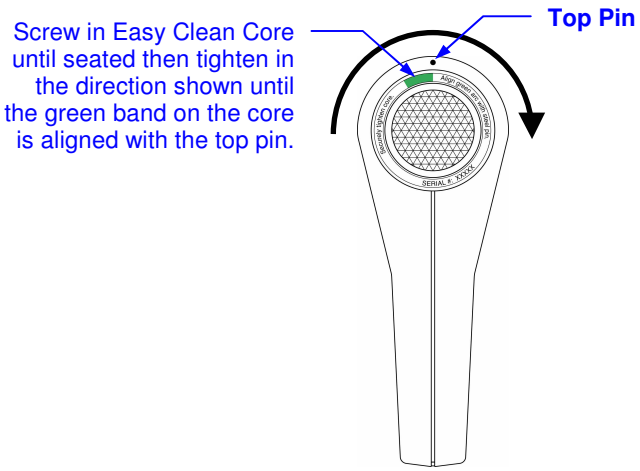

Screw in Easy Clean Core until seated then tighten in the direction shown until the green band on the core is aligned with the top pin.
Top Pin

Figure 8-2: *Alignment of Easy Clean Core*.

The figure below shows how to assemble the flow sensor.

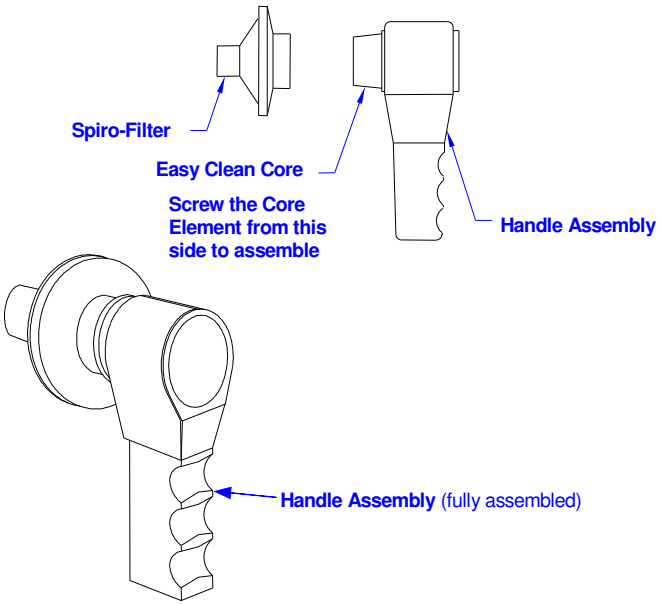


Figure 8-3: *Flow Sensor Assembly*.

8.2 SERVICE

If the instrument fails to work, do the following:

1. Ensure that the power to the computer is on and that all connections are secure.
2. Examine the unit for obvious loose, broken, or damaged components.
3. Check that the Easy Clean Core is tightened properly. (See Figure 8-2: *Alignment of Easy Clean Core*.)
4. Check that the Easy Clean Core is not blocked.
5. Check the computer communications port connection.

If the problem persists and the unit is within the warranty period, call Spirometrics at **800-767-0004**. Otherwise, please contact Spirometrics at **207-657-6700**. Our repair personnel can handle many problems over the phone.

Please be prepared to provide the information listed on the following page.

Product Model Number (PC Classic)	_____
Serial Number of Sensor (located on the bottom of the handle)	_____
Current hardware configuration including: CPU:	_____
Amount of RAM	_____
Size of Hard Drive	_____
Available Space on Hard Drive	_____
Type of mouse installed	_____
COM port	_____
Current software configuration, including: Operation system and version	_____
Is this computer on a network?	_____
Is the computer used for other purposes besides spirometry?	_____

If possible, be prepared to work with the device and its program while on the phone with technical support.

If the problem persists, the unit must be returned to Spirometrics for repair.

NOTE!

- You MUST call for an RGR number before returning your product for repair.
- Only Spirometrics and its service representatives are authorized to service equipment.

NOTES

APPENDICES

DEFINITIONS

Forced Vital Capacity (FVC) is a measure of the patient's expiratory vital capacity (the volume of air between a maximal inspiration and a maximal expiration). FVC indicates the greatest expired volume of air in a person's lungs. Note, however, that this vital capacity is derived from a forced expiration and dynamic compression of the airways may occur. Therefore, it may be different from the vital capacity derived from a slow expiration in a VC test.

Forced Expiratory Volume at One Second (FEV_1) is the volume of air exhaled in the first second of the FVC maneuver. It may be reduced in obstructive and restrictive processes. The **FEV_1/ FEV_6** ratio and **FEV_1/ FVC** ratio is needed to help determine the reason for the decreased FEV_1. FEV_1 is derived from the volume-time curve by finding the volume expired on the Y-axis of the curve at exactly one second into the test. However, if the maneuver had a slow start the PC Classic Plus automatically uses the Back Extrapolation Technique to determine the start of the test. One second is measured relative to the extrapolated start of the test.

Forced Expiratory Volume at Three Seconds (FEV_3) is similar to the FEV_1, but is measured at three seconds into the test, rather than one-second.

Forced Expiratory Volume at Six Seconds (FEV_6) is similar to the FEV_1, but is measured at six seconds into the test, rather than one-second.

FEV_1/FVC% is a ratio of FEV_1 to FVC. It is the FEV_1 divided by the FVC, then multiplied by 100 so that it can be expressed as a percentage. It is decreased in obstructive processes.

FEV_1/ FEV_6% is a ratio of FEV_1 to FEV_6. It is the FEV_1 divided by the FEV_6, then multiplied by 100 so that it can be expressed as a percentage. FEV_6 is used as a Forced Vital Capacity surrogate and is recommended by the National Lung Health Education Program (NLHEP). It is decreased in obstructive processes.

Forced Mid-Expiratory Flow ($FEF_{25-75\%}$) is the average forced expiratory flow over the middle 50% of the FVC curve, between 25 percent and 75 percent of the FVC.

Peak Expiratory Flow (PEF) or maximal expiratory flow is the highest point on the flow-volume curve. PEF should be at the very beginning of the curve; if PEF is after the beginning, the PC Classic Plus uses the Back Extrapolation Technique to determine the zero second point for the FEV_1 and FEV_3 calculations.

Forced Expiratory Flow (FEF_{50}) is the forced expiratory flow after 50% of the FVC has been exhaled.

Forced Inspiratory Vital Capacity (FIVC) is a measure of the patient's inspiratory vital capacity (the volume of air between a maximal expiration and a maximal inspiration). It is derived from a forced inspiration.

Forced Inspiratory Flow (FIF_{50}) is the forced inspiratory flow after 50% of the FIVC has been inhaled.

Ratio of FIF_{50} to FEF_{50} (FIF_{50}/FEF_{50}) is the Forced Expiratory Flow at 50% as a percentage of the Forced Inspiratory Flow at 50%, then multiplied by 100 to express the ratio as a percentage.

Peak Inspiratory Flow (PIF) is the maximum inspiratory flow anywhere on the inspiratory portion of the Flow-Volume Loop (below the zero line). PIF is the lowest point on the inspiratory portion of the Flow-Volume Loop.

Expiratory Time (ET) is the elapsed time, expressed in seconds, from the beginning of the expiration until the expiration is completed.

Maximum Voluntary Ventilation (MVV) is the largest volume of air inhaled or exhaled over a timed period, typically 12 to 15 seconds, which is then extrapolated to one minute. The maneuver done to measure the MVV should imitate rapid breathing during strenuous exercise.

Vital Capacity (VC) is the largest volume of exhaled gas measured on a slow complete expiration after a maximal inspiration.

Air Trapping Index (ATI) is the difference between the FVC and the VC indices. It may reflect how much air becomes trapped in the lungs during a forced expiration.

Lung Age is an estimate of the age of the subject's lungs based on spirometric measurements. The method used to estimate lung age is that described by Morris and Temple (*Preventive Medicine*, pp. 655-662, 1985.)

COPD Index is a measure of the subject's risk for developing COPD. To determine the COPD Index, the Tecumseh Index of Risk is calculated using the subject's age, gender, current smoking habits, FEV_1, and height according to the method described by Higgins and Keller (*Journal of Respiratory Diseases*, January, 1983).

Back Extrapolation Technique is necessary for the FEV_1 and the FEV timed. All flow related indices are affected when a back extrapolation error occurs.

NORMALS TABLES

The principal indication for spirometry testing is to determine whether a patient's pulmonary function is normal or abnormal. A **predicted normal** value for a spirometric test index is a prediction of the value a patient ***should*** attain if his/her pulmonary function is normal. The predictions are based on extensive studies of a population, and were often done by leading pulmonologists. To obtain predicted values, the technologist must enter the height, age, gender, and ethnic background of the patient. The spirometric test indices from thousands of people of varying height, age, gender, and ethnicity were analyzed and compiled into an equation. Each normals table is named by the pulmonologist who led the study.

The PC Classic Plus has normals tables from the following seven studies. When customizing your spirometer, select the table that you want to use (See Section 6.1 CUSTOMIZATION). The selected normals table should match the population to be tested as closely as possible. Note the applicable indices and ranges for each study.

NOTE!

When the table selected in Customization contains the indices: FVC, PEF and FEF 25-75, a predicted curve will be generated and displayed during testing and on reports. See the section 6.1.1 Software Customization for more information.

NHANES III

INDICES
FVC
FEV1
FEV6
FEV1/FVC
FEV1/FEV6
FEF 25-75
PEF

SEX	AGE Yrs: Min-max	HEIGHT cm: Min-max	HEIGHT in: Min-max
FEMALE:	8 – 80	*No stated limitation*	*No stated limitation*
MALE:	8 - 80	*No stated limitation*	*No stated limitation*

Knudson 1983

INDICES
FVC
FEV1
FEV1/FVC%
FEF 25-75
FEF 50

SEX	AGE Yrs -Min-max	HEIGHT cm - Min-max	HEIGHT in - Min-max
FEMALE:	6 - 10	106.7 - 147.3	42 - 58
	11 - 19	132.1 - 182.9	52 - 72
	20 - 69	147.3 - 180.3	58 - 71
	70 - 87	147.3 - 167.6	58 - 66
MALE:	6 - 11	111.8 - 154.9	44 - 61
	12 - 24	139.7 - 193.0	55 - 76
	25 - 84	157.5 - 195.6	62 - 77

Knudson 1976

INDICES
FVC
FEV1
FEV3
FEV1/FVC%
FEF 25-75
PEF

SEX	AGE Yrs -Min-max	HEIGHT cm - Min-max	HEIGHT in - Min-max
FEMALE:	8 - 79	*No stated limitation*	*No stated limitation*
MALE:	8 - 79	*No stated limitation*	*No stated limitation*

Crapo

INDICES:
FVC
FEV1
FEV3
FEV1/FVC%
FEF 25-75
MVV vol.

SEX	AGE Yrs - min-max	HEIGHT cm. min-max	HEIGHT in. min-max
FEMALE	17-84	146-178	57-71
MALE	15-91	157-194	61-77

Polgar

INDICES:
FVC
FEV1
FEF 25-75
MVV vol.

SEX	AGE Yrs - min-max	HEIGHT cm. min-max	HEIGHT in. min-max
FEMALE	6-18	*No stated limitation*	*No stated limitation*
MALE	6-18	*No stated limitation*	*No stated limitation*

ECCS with Knudson 1983
Children (ages 18 - 24 are evaluated as age 25)

INDICES
FVC
FEV1
FEV1/FVC%
FEF 25-75
PEF
FEF 50
FIVC
MVV vol.
VC

SEX	AGE Yrs: Min-max	HEIGHT cm: Min-max	HEIGHT in: Min-max
FEMALE:	25 - 90	145.0 - 180.0	56 - 72
CHILDREN (female)	6 - 10	106.7 - 147.3	42 - 58
	11 - 17	132.1 - 182.9	52 - 72
MALE:	25 - 90	155.0 - 195.0	58 - 80
CHILDREN (male)	6 - 11	111.8 - 154.9	44 - 61
	12 - 17	139.7 - 193.0	55 - 76

Morris

INDICES
FVC
FEV1
FEV1/FVC%
FEF 0.1 - 1.2
FEF 25-75
FEF 75-85

SEX	AGE Yrs: Min-max	HEIGHT cm: Min-max	HEIGHT in: Min-max
FEMALE:	20 - 84	145.0 - 180.0	56 - 72
MALE:	20 - 84	155.0 - 195.0	58 - 80

HSU 1979 (Using Journal of Pediatrics 1979)

INDICES
FVC
FEV1
FEF 25-75
PEF

SEX	AGE Yrs: Min-max	HEIGHT cm: Min-max	HEIGHT in: Min-max
FEMALE:	7 - 20	111 - 180	43 - 71
MALE:	7 - 20	111 - 190	43 - 75

LAM 1979 (Using Journal of Pediatrics 1979)

INDICES
FVC
FEV1
PEF

SEX	AGE Yrs: Min-max	HEIGHT cm: Min-max	HEIGHT in: Min-max
FEMALE:	5 - 74	*No stated limitation*	*No stated limitation*
MALE:	5 - 74	*No stated limitation*	*No stated limitation*

COMPOSITE

This is the Default normals selection. These normals provide predicted values for most indices.

INDICES	AUTHOR
FVC	NHANES III
FEV1	NHANES III
FEF 50	Knudson 83
FEV3	Crapo
FEV6	NHANES III
FEF 25-75	NHANES III
FEF 75-85	Morris
PEF	NHANES III
FIVC	NHANES III
FIF 50	No Predicted
PIF	No Predicted
FEV1/FVC	NHANES III
FEF 2-1.2	Morris
MVV	35 X FEV1 from NHANES III
VC	NHANES III

DIAGNOSTIC INTERPRETATION

The PC Classic can make simple diagnostic interpretations of the spirometric test data. The interpretation scheme is designed to distinguish normal from abnormal pulmonary function test results without making a diagnosis. Spirometry test data cannot stand by itself. It is important to coach patients to their maximal effort.

WARNING: Spirometry tests must be evaluated by a qualified physician. The interpretations printed by the PC Classic software are suggestive only and should not be considered conclusive.

The Summary Report, which is created by clicking on the **Summary Results** button in the **Browse Patient List** window, contains a box where interpretation information can be written. See section 5.6 Summary Report for more information. This box will also optionally contain a brief diagnostic summary generated by the PC Classic software. See section 6.1.4 Report Options to enable or disable this option.

Interpretations are based entirely on two indices: FVC and FEV1. The PC Classic uses the best of each of these indices from all test data for a particular patient.

INTERPRETATION TABLE

The following table describes the interpretation scheme and corresponding diagnostic messages:

% of Predicted			Interpretive Message
FVC	FEV1	FEV1/FVC	
	< 75%	≤ 75%	Low FEV1 Suggests Obstructive Disorder
	< 60%	≥ 75%	Low FEV1 Suggests Ventilatory Disorder
< 75%		≥ 75%	Low FVC Suggests Restrictive Disorder
< 60%		< 75%	Low FVC Suggests Ventilatory Disorder
In all other cases spirometric results appear normal			

REFERENCES

STANDARDS AND GUIDELINES:

American Thoracic Society Pulmonary Laboratory Management and Procedure Manual. New York: ATS; 1998. (Updated chapters are available each year.)

American Thoracic Society. Standardization of spirometry-1987 update. Am Rev Respir Dis 1987; 136:1039-1060. Published concurrently in Respir Care 1987;32(11): 1039-1060.

American Thoracic Society. Standardization of spirometry 1994 update. Am J Respir Crit Care Med 1995; 152 (3): 1107-1136.

American Thoracic Society. Lung function testing: Selection of reference values and interpretative strategies. Am Rev Respir Dis 1991; 144: 1202-1218.

American Thoracic Society. Guidelines for methacholine and exercise challenge-1999. Am J Respir Crit Care Med 2000; 161: 309-329.

American Association for Respiratory Care Clinical Practice Guideline: Spirometry, 1996 update. Respir Care 1996;41:629-636.

American Association for Respiratory Care Clinical Practice Guideline. Methacholine Challenge Testing: 2001 Revision and Update. Respir Care 2001; 46(5):523-530

National Committee for Clinical Laboratory Standards. HS-4, Approved document. A Quality System Model for Respiratory Care. Wayne, PA: NCCLS; 2002.

ADDITIONAL RESOURCES:

Eaton T, Withy S, Garrett JE, Mercer J, Whitlock RML, Rea HH. Spirometry in primary care practice: The importance of quality assurance and the impact of spirometry workshops. Chest 1999;116: 416-423.

Enright PL, Johnson LJ, Connett JE, Voelker H, Buist AS. Spirometry in the Lung Health Study: methods and quality control. Am Rev Respir Dis 1991;143:1215-1223.

American College of Occupational an Environmental Medicine Position Paper. Spirometry in the occupational setting. ACOEM. 2000.

Ferguson GT, Enright PL, Buist AS, Higgins MW. Office Spirometry for Lung Health Assessment in Adults: A Consensus Statement From the National Lung Health Education Program. Chest 2000 117: 1146-1161.

Wanger J, Irvin C. Office spirometry: equipment selection and training of staff in the private practice setting. Journal of Asthma 1997; 34(2), 93-104.

SPIROMETRY WEBSITES:

American Thoracic Society www.thoraic.org

American Association for Respiratory Care www.aarc.org

National Lung Health Education Program www.nlhep.com

National Lung Health Education Program www.nlhep.com

Global Initiative for Chronic Obstructive Lung Disease: www.goldcopd.com

PRODUCT LIST

ACCESSORIES:

Item#	Description	Packaging
2195	Spiro-Filter	Box of 100
2104	Nose Clips	Bag of 10
20043	Pediatric Adapter	Bag of 1
3014	Pediatric Mouthpiece	Bag of 100

EDUCATIONAL PRODUCTS

Item#	Description
SP-061973	*Spirometry: Producing Quality Test Results* CDROM
SP-040151	*Diagnostic Training and Competence Manual: Pulmonary and Noninvasive Cardiology* CD-ROM containing manual
SP-111680	*Spirometry Quality: The Essentials* Printed Version
SP-081570	*Spirometry Quality: The Essentials* CD-ROM Version
SP-101201	*Spirometry: Test Quality Assessment Selecting and Reporting Results* Video and Workbook
SP-070402	Additional Workbook for SP-101201

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